FUNCTIONAL OUTCOME ANALYSIS OF SKELETAL STABILISATION IN PATHOLOGICAL FRACTURES – A PROSPECTIVE AND RETROSPECTIVE STUDY

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CERTIFICATE

This is to certify that this dissertation titled **"Functional Outcome Analysis of Skeletal Stabilisation In Pathological Fractures – A Prospective And Retrospective Study"** is a bonafide record of work done by **Dr. K. Sunil Kumar,** during the period of his post graduate study from June 2012 to September 2014 under guidance and supervision in the INSTITUTE OF ORTHOPAEDICS AND TRAUMATOLOGY, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai-600003, in partial fulfillment of the requirement for **M.S.ORTHOPAEDIC SURGERY** degree examination of The Tamil Nadu Dr. M.G.R. Medical University to be held in April 2015.

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DECLARATION

I declare that the dissertation entitled **"FUNCTIONAL OUTCOME ANALYSIS OF SKELETAL STABILISATION IN PATHOLOGICAL FRACTURES – A PROSPECTIVE AND RETROSPECTIVE STUDY"** *submitted by me for the degree of M.S is the record work carried out by me during the period of* ***june 2012 to September 2014*** *under the guidance of* ***PROF.N.DEEN MUHAMMAD ISMAIL M.S.ORTHO.,D.ORTHO.,*** *Professor of Orthopaedics, Institute of Orthopaedics and Traumatology, Madras Medical College, Chennai. This dissertation is submitted to The Tamilnadu Dr.M.G.R. Medical University, Chennai, in partial fulfillment of the University regulations for the award of degree of M.S.ORTHOPAEDICS (BRANCH-II) examination to be held in April 2015.*

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ABSTRACT

(Key words – Pathological fractures, metastases, skeletal stabilization, bone tumors, malignancy, custom prosthesis)

Study title

Outcome analysis of skeletal stabilization in pathological fractures- a short term prospective and retrospective study.

Background

Pathological fractures of the long bones are a common complication of metastatic disease caused by skeletal metastases and variety of primary malignant bone tumors. The incidence of the metastatic bone deposits by primary malignancies has been reported in up to 50% of the patients. Surgery is indicated for intractable pain, impending or established pathological fractures. However, the majority of studies are retrospective and do not evaluate the functional improvement.

Aim of the study

This study is to evaluate the functional outcome after skeletal stabilization of fractures in patients, who sustained pathological fractures secondary to skeletal metastases, also fractures which occur at the site of primary malignant bone tumors.

Patients & methods

We studied prospectively and retrospectively a consecutive series of patients with pathological fractures of the long bone and spine treated between

2012 and 2014. Preoperatively all patients had a bone scan or a skeletal survey to assess the integrity of the remaining skeleton, and to avoid fracture of occult bone metastasis and all patients underwent basic blood investigations to confirm skeletal metastasis like serum calcium, alkaline phosphatase, phosphorus, PSA, thyroid profile, urine BJP & serum protein electrophoeresis. And other radiological investigations like USG abdomen, CT chest and CT abdomen and pelvis. Surgical treatment consisted of intramedullary (IM) nailing in 4 patients, prostheses in 6 patients, plating in two patients, posterior stabilization in 4 patients, DCS in 2 patients and arthroplasty in 2 patients. Functional status was assessed with the 1987 and 1993 versions of the Musculoskeletal Tumor Society (MSTS) functional assessment forms.

Results

Our findings showed an increase in the bodily pain score at 6 weeks and 12 weeks postoperatively, which is consistent with better pain control. Significant improvement in post operative MSTS scores at 6 weeks, 3 months, 6 months and one year postoperatively which shows better functional outcome. Our study shows low incidence of postoperative complications, reduction of pain, improvement in the quality of life and early ambulation, which strongly support operative treatment of pathological fractures of long bones in patients with bone metastases. Better results can be achieved with team approach by orthopedician, oncologist, radiologist and physiotherapist.

Conclusion

However, early improvement in functional status, better pain control, early ambulation and relatively much lesser complication rate, we strongly recommend surgical stabilization for pathological fractures.

Better results can be achieved with team approach including orthopaedic surgeon, oncologist, radiologist and physiotherapist.

The timing of the surgery is always of paramount importance in these patients. It solely depends up on the patients' general condition, however should be done at the very first safe opportunity.

CONTENTS

INTRODUCTION

Bone metastasis is the most common complication in patients with cancer. Skeleton is the third most common site for metastases after pulmonary and breast metastases(1). Studies show one in every five patients suffering from cancer can have symptomatic bone metastases (2). The incidence of metastasis and pathological fractures have been reported in up to 50% of patients suffering from cancer(3). Pathological fractures account for a significant economic burden on the health care system of our country(4). The intractable pain and functional limitation are the two major manifestations of skeletal metastases and pathological fractures.

Pathological fractures can be defined as fracture that occurs at the site of metastasis or at the site of primary malignant bone tumor.

Pathological fractures can be a complication of most of the primary malignant tumors of bone, but majority of pathological fractures are secondary to metastatic process of established

malignancy. Common systemic malignancies which can spread the disease to human skeleton are breast, lung, prostate, renal and thyroid malignancies. Metastases and subsequent pathological fractures can hamper both the quality of life and also functional capacity of the patient.

Prognosis of patients suffering from pathological fractures entirely depends on the stage of the primary disease. Cure does not always depend on the early diagnosis and management. But early interventions can reduce the morbidity caused by metastases, which in turn improves the quality of rest of the life lived by the patient.

Metastatic process is mainly influenced by cellular biologics and molecular characteristics of host and malignant cell. Other factors which can influence this process are blood flow and vascular pathways. Many times skeletal metastases can be found without any lesions in lung or other solid organs. Which clearly makes a point that, vascular pathways are significant contributors in metastases.

Almost half a decade ago, Batson in his study on cadavers proved that venous blood coming from breast, pelvis and other solid abdominal organs not only reached venacava but also had connections to vertebral venous plexus. Which proves that metastases can bypass solid organs to reach skeleton.

In the past pathologic fractures of the extremities due to metastasis or malignant bone tumors were the absolute indications for amputations of the limb (6,7). Amputations have been traditionally recommended for malignant bone tumors and pathological fractures due to metastasis bases on the theory that fracture induced hematomas can increase the risk of micro metastasis (8,9). This theory lead to the observation that pathological fractures were directly linked to the prognosis and high mortality rates (10). Several recent studies demonstrated that pathological fractures have no prognostic significance in patients suffering from high grade malignant tumors (11, 12). Such fractures are also poor indicators of recurrence risk,

though significantly associated increased mortality rate has been reported (13).

These patients will be having shortest estimated life span than other patients (14). We should give important to this before considering surgery. Goal should be shorter recovery period from surgery than expected survival (15). A study by Parrish and Murray reported that these patients should have minimum of 6 weeks of average estimated life span before considering surgery.

A metastatic disease is not a life threatening process, but it can decrease the quality of life, also functional status of patient. Pain , anxiety and depression should be equally considered and properly treated. Surgery in these patients is meant mainly to reduce pain, early ambulation and better stability, which also substantially improve the functional status and quality of life left.

In these patients with very limited life expectancy, importance must be given to immediate pain relief and improving functional status.

Number of studies have been conducted to prove the benefits of surgery (17,18,19,20).

We evaluated prospectively, also retrospectively the functional outcome of patients with pathological fractures managed with surgical stabilization.

AIM OF THE STUDY

This study is to evaluate the functional outcome after skeletal stabilization of fractures in patients, who sustained pathological fractures secondary to skeletal metastases, also fractures which occurs at the site of primary malignant bone tumours.

REVIEW OF LITERATURE

A Pathological fracture also addressed as a secondary fracture or a spontaneous fracture was first described by Grunet in 1905, he defined it as a fracture due to weakening of bone structure by a pathologic process (21,22). These pathological fracture are usually caused by minimal forces and it was described by Miller in 1850 when he wrote " on some light exertion , as turning in bed , a bone broke".

Cortical bone lesions have been found in radiological analysis of Egyptian mummies which are very likely due to metastasis. Long bone metastasis and pathological fractures have been found in French specimen dated 700 A.D.

"Rotting the bones under them" due to bone metastases was described by Wiseman in 1677. Several acute pathological fractures of long bones due to breast cancer was studied by Cooper in 1825. Conservative treatment modalities like cast immobilization or skeletal traction had

very little effect in relieving pain or encouraging early mobility of the patient.

Leuzinger in 1886 described a large variation in the functional outcome after surgery on a group of patients who sustained pathological fractures due to metastases. The next move was made by Haase in 1943, who first did intramedullary nailing in a case of pathological fracture shaft of femur due to metastases from a renal carcinoma. In the subsequent decades various surgical fixation modalities were improvised due to development of technique of plate osteosynthesis (23).

Francis KC in 1960 in his study on a series of 80 patients of pathological long bone diaphyseal fractures were successfully treated by intramedullary nailing and also by plate osteosynthesis. Parrish and Murray in 1970 threw light over additional use of bone cement (methylmethacrylate), especially in filling of cavity after tumor removal,

also in rigid stabilization of pathological fractures with extensive bone destruction (24, 25).

Galasko CSB in 1974 introduced the technique of cemented hemiathroplasty for proximal femoral pathological fractures, and gave large variations in the functional outcome of patients with femoral neck pathological fractures treated by this technique.

Although various treatment modalities have been introduced in the management of metastatic bone lesions like radiotherapy, chemotherapy and improvised surgical techniques, the problem arises whether and when a pathological fracture should be fixed internally. Griesmann and Schiittemeyer in 1947 described the benefits of prophylactic fixation of pathological fractures (26). Various authors have described about impending pathological fractures. Parrish and Murray in 1970 said, increasing pain with advancing cortical destruction involving more than half of the shaft diameter. Beals in 1971 described it as, a lesions more than 2.5cm are at increased risk to pathological

fracture. Murray in 1974 described it as there is increased incidence of pathological fracture with cortical destruction of more than half of the diameter and persistent pain even after radiotherapy.

In the subsequent decades criteria for fixation of pathological fractures have been described by various authors. To name a few, Fidler in 1981 concluded it as prophylactic internal fixation should be considered if there is more than 50% cortical destruction by tumor or metastases(27). Harrington in 1985 drew a criterion based on his study on 118 patients of skeletal metastases(28). According to him prophylactic internal fixation should be considered if the lesion measures more than 2.5cm, more than 50% cortical destruction, fracture of lesser trochanter and persistent pain even after radiotherapy. There are certain limitations in his study such as it accounts only for proximal femoral lesions and it does not account for tumor biology. His limitations lead further research by Mirels who concluded it in 1989 and which is being used as a standard criteria for

considering a patient of pathological fracture for prophylactic internal fixation(29).

Mirels Scoring System			
	1	2	3
Place of metastases	Upper limb	Lower limb	Proximal femur
Severity of pain	Tolerable	Need analgesics	Intolerable
Nature of lesion	Blastic	Both blastic and lytic features	Lytic
Size of lesion	<1/3 Of cortical diameter	1/3-2/3 of cortical diameter	>2/3 of cortical diameter

Involved bone should be stabilized if the score is more than or equal to 7.

The aim of this study is to analyse the functional outcome in surgically treated patients who sustained pathological fractures due to skeletal metastases from any solid organ malignancy or, tumors at the

site of fracture. Based on this the following studies have been conducted in the past.

Following are the studies to support this work on pathological fractures. PDS Dijkstra, T Wiggers, BN van Geel and H Boxma in 1994 conducted a study of 200 patients of pathological fractures who underwent surgery and analysed their functional outcome. Behur JT, Danbozi WR, Bandarinath K in 1985 did a study on surgical stabilization of proximal femoral pathological fractures. That was a series study on 124 patients with good outcome and which strongly supports surgical stabilization in pathological fractures. Borel Rinkes IHM, Viggers T, Bouma VH, van Geel AN, Boxma H in 1990 did a study called ' Treatment of pathologic fractures of the femoral neck by cemented hemiarthroplasty, which has threw light over management of juxta-articular fractures by arthroplasty.

PATHOLOGICAL FRACTURES – AN OVERVIEW

Skeleton is the commonest site for metastases. Commonly involved other solid organs like lung, breast, GIT and renal. (30). Metastases are more commonly diagnosed in elderly patients above 50 years, than any other primary malignancy. No primary tumor is found in about ten percent of cases. Blood is the main route of spread of metastases. Some solid organ tumors can directly invade adjacent bones (eg. Pelvis and ribs). Metastases are more commonly osteolytic, and bone resorption may be either due to tumor derived factors or due to direct action of tumor cells. Osteoblastic lesions are less common and are usually due to prostatic carcinoma.

Pathological fracture can be defined as fracture which is secondary to skeletal metastases from any metastatic malignant tumors of the body , also fracture which occurs in the area of primary malignant bone tumors.

The probability of developing pathological fractures is directly associated with duration of metastatic involvement of bone. Development of pathological fracture in a cancer patient is debilitating and devastating. Emphasis is now being placed on early identification of skeletal involvement by screening procedures in cancer patient, which helps in prophylactic fixation of fragile bones and preventing further pathological fractures.

Location of metastases :

Metastases are usually multifocal, however solitary metastases are not uncommon. Vertebral metastases are much more common than the primary tumors of vertebra or spinal cord, specially in elderly age groups(31). An autopsy study series on patients who died of cancer showed one-third of them had vertebral metastases (32). Anterior elements' metastases are more commoner than the posterior elements (33).

60% of patients diagnosed with cancer may already have skeletal involvement of metastases. 10 – 15% of all patients with primary carcinoma will show radiologic evidence of bone metastases during the course of disease.

Metastases may spread by various routes, either contiguous, hematogenous or through lymphatic channels. Hematogenous route is more common mode of spread of the disease.

Incidence of metastases at autopsy by various primary tumors

Primary site	Percentage of metastases to bones
Breast	50 – 85%
Lung	30 – 50%
Prostate	50 – 70%
Hodgkin's lymphoma	50 – 70%
Kidney	30 – 50%
Thyroid	40%
Melanoma	30 – 40%
Bladder	12 – 25%

Mechanism of metastases:

During the course of tumor or cancer, the detached cells from the primary site may invade vascular channels or lymphatics, which further get disseminated to various sites and get attached to endothelial cells of organs, which further leads to angiogenesis and tumor growth at distant site. These metastases may be lytic, blastic or mixed depending up on the characteristic features of primary tumor or cancer.

Clinical features and presentation :

For all patients of age above 50 years, presenting with signs of destructive bone lesions, metastases should be suspected and properly investigated. These patients can have varied presentations. Metastatic lesions may be quiescent without any revealing signs or may be painful to disabling. Sometimes these lesions are detected in imaging studies done for some other musculoskeletal pain. Metastases is not always confined to skeleton, sometimes it can present with mere soft tissue swelling, in which a suspicion of sarcoma is valued.

Pain is the most common and sometimes the only presenting feature in patients with metastases. Most of the patients with metastases, will be having severe pain that is usually unresponsive to the routine analgesics; which mandates to use narcotics. In patients having spinal metastases and related nerve root compression, the only presenting feature may be altered sensation or motor weakness. Patients with pelvic metastases or tumors arising from pelvis, may present with mere leg pain which mimics sciatica. A basic investigation like high quality radiograph of pelvis should not be neglected in these patients that helps in detecting bony metastases and tumors of pelvis as magnetic resonance imaging of spine can often fail to detect these lesions. Biopsy from the affected site is greatly helpful at diagnosis in those who present with sudden collapse of a vertebra or any long bone fracture after trivial trauma without evidence of primary cause. Symptoms of hypercalcemia may occur during the period of skeletal metastases, which includes abdominal pain, nausea, anorexia, thirst, polyuria, depression and general weakness. Hypercalcemia if left

untreated may follow serious consequences in these patients, like nephrocalcinosis, renal acidosis, unconsciousness and encephalopathy. It can be managed by adequately hydrating, and correcting serum calcium level. Bisphosphonates do have a positive role here. Clinical evaluation of patients before any investigation, does make an important part in managing these patients with pathological fractures, not only to elicit signs to support the diagnosis but also to make a search for any hidden clues for metastases or primary malignant lesion, where exactly the treatment should be targeted. A regular follow up and radiological screening is mandatory, in case of patients with previously diagnosed and treated metastases to look for future spread of the disease and impending pathological fractures.

Osteolysis secondary to metastases:

Bone metastases can be classified on their radiological appearance as lytic, blastic or mixed ones. Lytic lesions are those in which bone resorption predominates osteogenesis. Metastases

secondary to thyroid, lung, renal and gastrointestinal malignancies produces lytic lesions. On the contrary where osteoblastic activity predominates osteolysis lesions take sclerotic appearance and is commonly seen in metastases secondary to breast tumors, prostate malignancy, carcinoid and medulloblastomas. Bone markers in malignancy do have an important role in diagnosis as well as objective assessment of effect of tumor on bone.

The following tabulation gives an overview of bone markers excreted in breast, prostate and other tumors.

	Breast (n=29)	Prostate (n=10)	Other (n=7)
N terminal telopeptide	2.55	7.61	3.19
Crosslaps	1.84	4.93	2.86
Free deoxypyridinoline	2.22	3.19	2.47
Hydroxyproline	1.66	2.92	2.27
Urinary calcium	0.78	1.77	2.46

The above data has been expressed as a mean value for a patient respective to their age and sex based controls. Even though the excretion of calcium in all three groups is less significant, all three groups showed an accelerated bone destruction irrespective of radiological appearance of their disease. The above data also shows the

significant bone resorption in prostatic carcinoma even though tumor matastases is sclerotic in nature.

Imaging in pathological fractures:

A high quality plain anteroposterior and lateral radiographs, which covers one joint above and below the involved segment of bone, is the standard initial assessment for all kinds of metastatic disease and pathological fractures. This will reveal the nature of metastases if lytic, mixed or blastic type. Metastases from lung, kidneys and thyroid are mostly lytic lesions (fig – 1). Metastases from carcinoma breast more often will be lytic however a mixed presentation like lytic-blastic type can also occur (fig - 2).

Fig – 1, AP radiograph of pelvis with both hips showing pathological subtrochanteric fracture left femur due to metastases from renal cell carcinoama.

Fig-2,AP and lateral radiographs showing multiple lytic and blastic metastases and pathological wedge compression fracture of L1 vertebra from medullary carcinoma of breast.

Along with routine APand lateral views of pelvis, radiographs should also include obturator oblique and iliac oblique views. A metastatic lesion to appear on radiographs, there should be significant amount of bony destruction, even when the lesion is solitary. So all patients suffering from pathological fracture due to metastases requires further evaluation despite innocent appearance of normal x rays. Computed tomography is the study of choice to asses the amount of cortical destruction however less sensitive in assessing marrow involvement and its extension (fig – 3). Best investigation for assessing marrow involvement of the disease is Magnetic resonance imaging (MRI); with good sensitivity, which detect the metastases even before their appearance on radiographs (fig – 4). However MRI is not an investigation to study bone anatomy, which is done better by CT scan.

Fig – 3, 3D reconstruction images of pelvis showing pathological fracture neck of femur of a patient due to giant cell tumor.

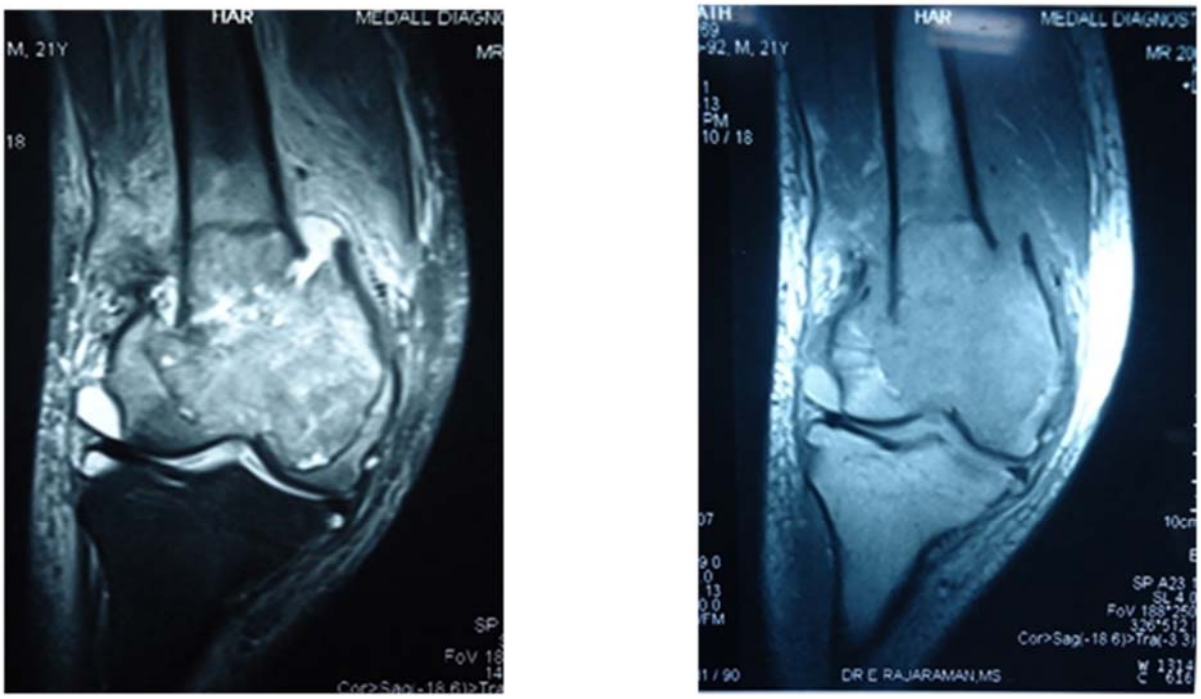


Fig – 4, MRI images of knee joint, showing pathological fracture of distal femur due to giant cell tumor, marrow replacement can be noticed.

Whole body radionuclide bone scan with 99mTc-MDP is very useful tool in searching for distant and silent skeletal metastases. Radionuclide scan is a precise investigation to detect all the hidden distant metastases which sometimes is unnoticed by routine plain radiographs. It has very low specificity, as radionuclide accumulation occurs even at infective foci, degenerative areas of bone and benign bone conditions like fibrous dysplasia and hemangioma, which shows osteoblastic activity and are falsely mistaken for metastatic foci. False negativity is not uncommon in bone scan, as in plasma cell myeloma and neoplasms which are confined to medullary cavity only, where osteoclastic activity exceeds osteoblastic function (fig – 5).

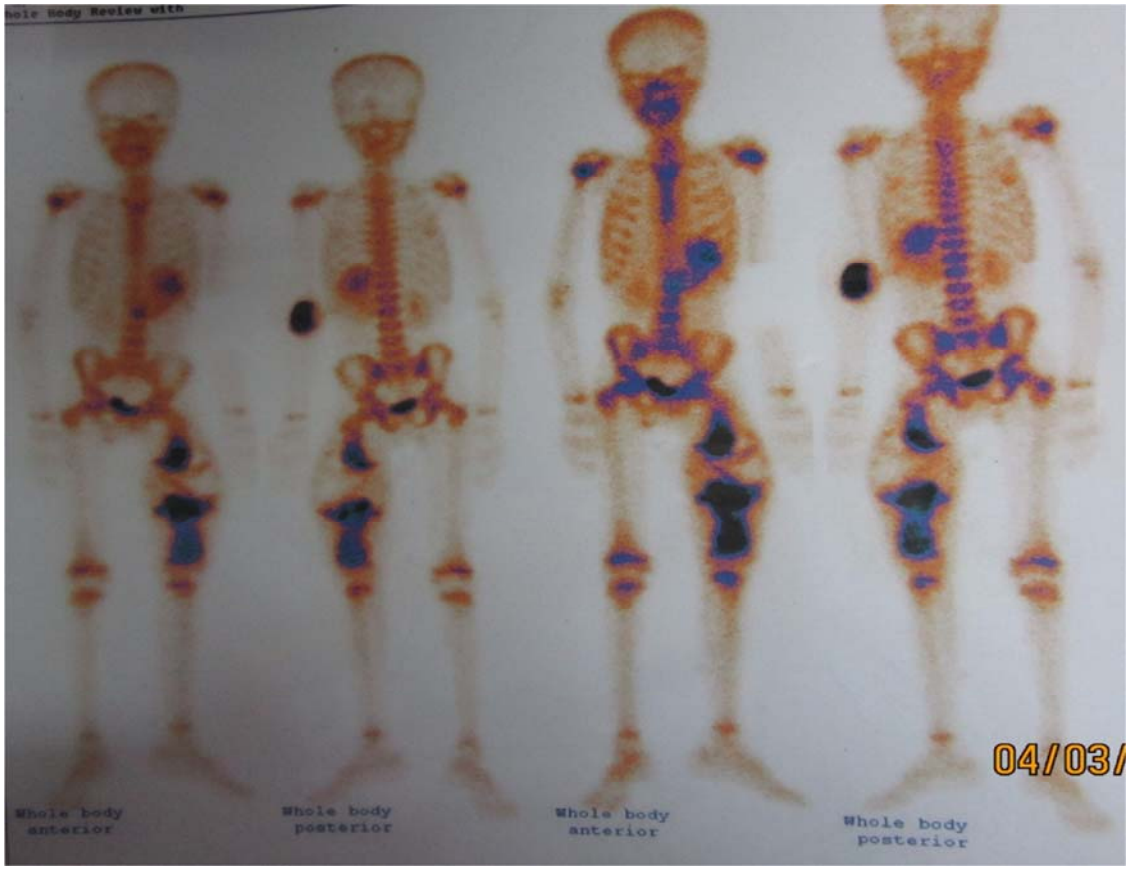


Fig – 5, Whole body radionuclide bone scan of a 9 year old male child with high grade osteosarcoma of left femur with multiple metastatic deposits.

Diagnostic laboratory tests in pathological fractures:

Various blood parameters, tumor markers and some specific protein analysis in patients with pathological fractures play very important role, especially when these patients present with unknown primary malignancy.

A complete haemogram with differentiated white cell count often helps in diagnosing tumor based inflammation in the body, anemia and thrombocyte count.

An active inflammation can be detected by raised erythrocyte sedimentation rate and C-reactive protein levels, but these tests lack in capacity to differentiate between malignancy and infectious processes.

Serum alkaline phosphatase is an indicator of skeletal metastases, however elevated values may also be sometimes seen in benign conditions.

Carcinoembryonic antigen is an absolute marker for detecting adenocarcinoma of breast, pancreas , gastric, colon and rectal origin.

Prostate specific antigen (PSA) helps in diagnosing prostate cancer with good specificity.

A thyroid panel investigation helps at detecting primary pathology from thyroid glands, however is having poor specificity in differentiating malignant thyroid lesions from those of benign.

Lactate dehydrogenase may be elevated in patients having lymphomas as primary cause, specially their isoenzymes LDH - 2 and LDH - 3.

Elevated serum alpha fetal protein is seen in hepatic metastases, also in hepatitis-C and heavy drinkers.

Renal function tests often helps in assessing renal functions and serum Ca 2+ and phosphate levels should be monitored and followed up to diagnose and prevent malignant hypercalcemia. Bone collagen breakdown indicator, urinary N-telopeptide often parallels tumor burden.

MANAGEMENT OF PATHOLOGICAL FRACTURES:

Treatment of pathological fractures is a challenge. By the time patients present to us with wide spread skeletal metastases and pathological fracture, it is understood that prognosis will be poor with reduced survival rate. A multimodal approach which includes chemotherapy, radiotherapy and surgical stabilization of fracture, mainly targeting the metastatic foci or fracture site and the primary disease process, will be always rewarding and even partially curative in some ways, like bringing down the malignant activity. However treatment will be mostly surgical stabilization of fracture and symptomatic relief for patients with pathological fractures with multiple secondaries.

Baeur's criteria for survival in case of pathological fractures

Baeur in 1995 introduced criteria for assessing prognosis in these patients.

Positive criteria by Baeur's for survival

1. A single metastatic focus
2. Without break in the cortex
3. No solid organ involvement
4. Primary pathology in breast or kidney
5. Without pulmonary involvement

In study on series of patients with pathological fractures, survivorship for one year is as follows.

Baeur's positive criteria	**Survivorship of 1 year, in percentage**
4 – 5	50%
2 – 3	25%
0 – 1	<25%

Palliative treatment :

Patients should be made comfortable, to enjoy their remaining period of life and die in a peaceful and dignified manner. More than anything, practical assistance and sympathetic support makes very important part of management.

Analgesics are being advised for all patients suffering from cancer pain, however narcotics are usually reserved for uncontrolled pain and in case of terminally ill patients. Radiotherapy should be the treatment of choice to control pain and to stop or slow down the neoplastic progression, unless specifically contraindicated. Post operatively, chemo-radiation should be avoided for about one to two weeks for unimpeded wound healing.

Not all the metastases are equally sensitive to chemoradiation therapy:

Breast	Radiosensitive & chemosensitive
Lung	Moderately radiosensitive & variable chemosensitivity
Prostate	Radiosensitive & chemosensitive
Thyroid	Radiosensitive & chemosensitive
Renal	Minimally radiosensitive & variable chemosensitivity
GI tumors, melanoma	Radioresistant & moderately chemosensitive

For treating secondary deposits in limbs, single dose of around 8Gy to 40Gy over fifteen fractions is sufficient. Single large dose can be used for pain alleviation and fractional doses over a period of time provides a huge cumulative dose, which is commonly reserved for definitive treatment in suppressing metastatic activity and reducing the tumor size.

Hormonal therapy can be used to control the activity of secondaries from breast and prostate malignancies. Androgenic agents or oestrogens for breast secondaries and stilboestrol for prostate

secondaries are helpful. Disseminated secondaries from carcinoma of breast can be very well managed by surgical interventions like, adrenalectomy, oophorectomy and hypophyseal ablation when medical line of management fails.

Bisphophonates do have a positive role in inhibiting osteoclastic activity and balancing the osteoclastic activity with osteoblastic activity thus are commonly advised along with chemotherapy in treating destructive bone lesions. In conjunction with systemic chemotherapy, palmidronate is used in metastatic disease and pathological fractures. This has been shown to reduce chances of future bone resorption and pathological fractures especially in patients with breast carcinoma and multiple myeloma.

Hypercoagulability and deep vein thrombosis (DVT) are the two complications which makes the treatment troublesome in these patients who usually require prolonged immobilization, also in patients with multiple myeloma as primary cause. So DVT prophylaxis with

pharmacological agents and interventional devices like compression devices and vena cava filters, should always be a part of the treatment in non ambulatory patients.

Surgical management of pathological fractures:

Pathological fractures in elderly patients are always devastating and is an absolute indication for fixation. Patient's overall general condition, co-morbid factors and estimated average life span should always be given priority before considering for surgical intervention. According to a study conducted by Parrish FF & Murray JA in 1970, on 96 patients with secondary neoplastic fractures, they concluded that minimum 6 weeks of average expected life span should be present before considering such patients for surgical intervention.

Surgical treatment of pathological fractures is not as easy as operating on a normal bone. Because of poor bone quality, loss of bone segment due to destruction by metastases or by tumor alone makes the fixation process very difficult. Choice of implant should be patient

specific and if necessary augmenting agents like methyl – methacrylate and bone grafts should be used in the procedure.

Pathological fractures are extremely detrimental and they need prophylactic fixation. The criteria have been laid down by Mirels' in 1989. Risk of fracture in a bone with already established metastases can be estimated by using this scoring system. This system is based on size of the lesion, pain, nature of the lesion and anatomic location. Mirels' recommended prophylactic fixation for a score of 9. More reliable predictor of pathological fracture is pain at the site of metastases.

Whenever a tumor presents with a pathological fracture, definitive surgical procedure should always be preceded by histological confirmation of the primary lesion by biopsy. Reaming medullary canal specially in intramedullary nailing for long bone shaft fractures may result in distal seeding of malignant cells and might finally end up with amputation of the limb. So if it is a sarcoma, definitive treatment

should be surgical clearance by excision and reconstruction by custom made mega prosthesis.

The goals of surgery in pathological fractures are to alleviate pain, to ensure a well functioning and durable construct which makes the patient ambulant as early as possible. Metastases induced bone destruction , age related osteoporosis and suppressed ability of healing in a bone, makes the treatment challenging. So it is impossible to apply the same techniques and principles of fixation in pathological fractures which are being used in surgical fixation in normal population, where the fixation is mere a temporary measure to support the natural bone healing. The main goal behind surgical fixation of pathological fractures is to supplement pathologically compromised skeleton with a functionally stable and mechanically durable construct. This can be achieved by using intramedullary rods and specialized locking compression plates with or without using autografts, allografts or methyl methacrylate as supplements for better fixation of the implants,

over compromised and weak bones. Introduction of arthroplasty in pathological fractures specially when the fractures occurs at or near the joint, is a huge success and provides better stability than any other mode of fixation because of stable construct, less operative time and least amount of blood loss.

Sometimes in case of pathological fractures due to malignant bone tumors, where tumor clearance is mandatory, a custom made mega prosthesis can be used after surgical clearance of the tumor and which gives segmental replacement of diaphysis and also joint surface. These prosthesis do play a very important part in treating pathological fractures due to primary bone tumors, where large amount of bone loss is expected.

Fig – 6a

Fig – 6b

Fig – 6c

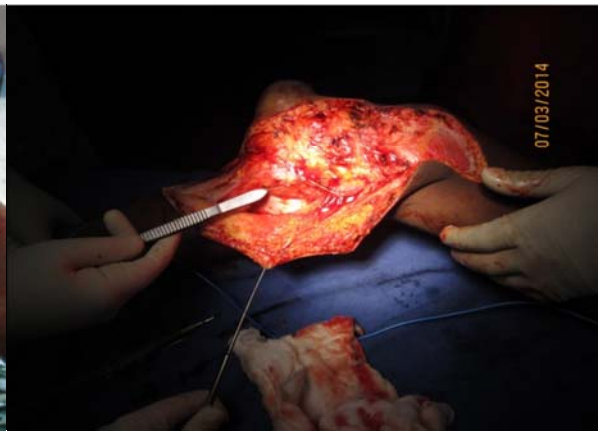


Fig - 6d

Fig – 6e

Fig – 6f

Fig – 6g

Fig – 6h

Fig. 6a & 6b, radiographs showing pathological fracture of right proximal tibia due to osteosarcoma. Fig 6c to 6f, pre operative and per operative clinical pictures of the patient. Fig 6g & 6f, post operative radiographs.

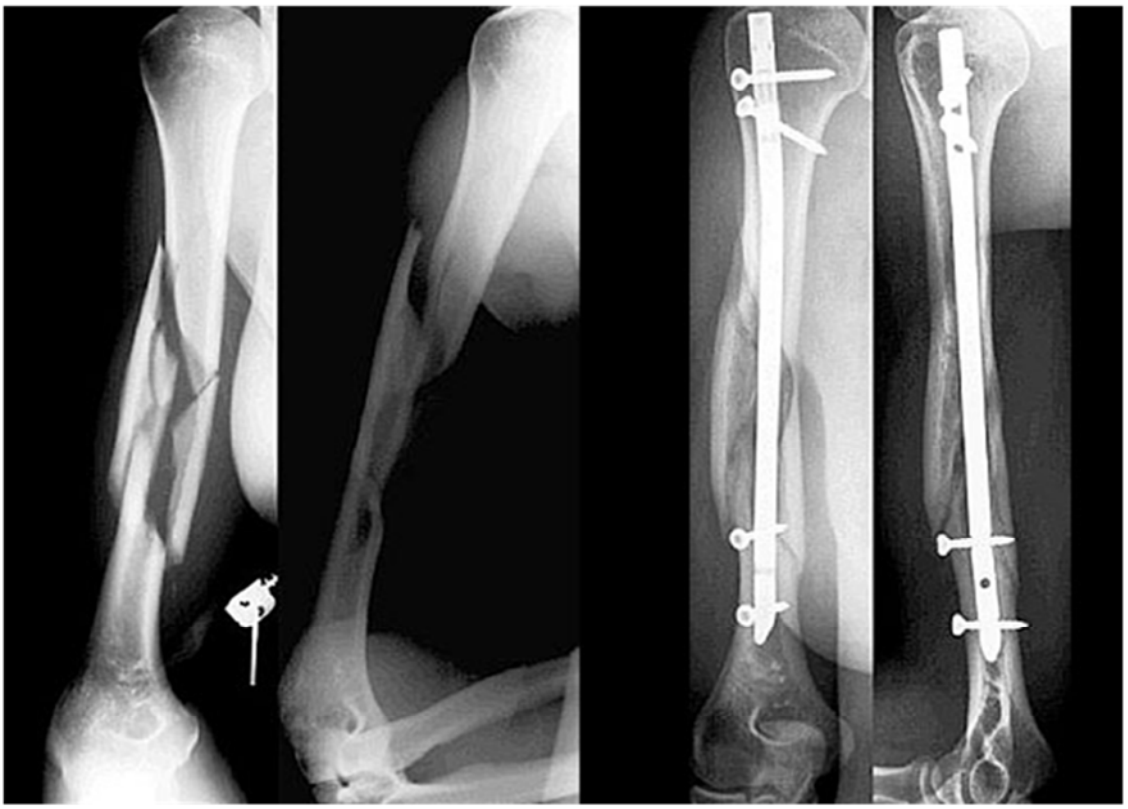


Fig – 7, Radiographs showing intramedullary fixation of pathological fracture of shaft of humerus.

Studies have proven that intramedullary fixation of long bones pathological fractures is stable and durable than treating them with extramedullary plate osteosynthesis, where chances of hardware failure are much more common than the former.

Metastatic spinal disease and pathological vertebral fractures are 40 times more common than primary spinal tumors. The goals of intervention are to decrease pain, make the patient ambulatant by preserving power of limbs, maintaining urinary, faecal continence and to prolong survival. If the fracture is stable and without neurological deficits it can be managed by a well fitting brace. However vertebral fractures cause a significant morbidity due to pain, instability and neurological deficit. For such patients operative stabilization is definitely indicated in the form of posterior instrumented stabilization or spinal fusion anteriorly, depending on the individual need. Pre operative workup in these patients includes, AP and lateral radiographs of affected level of spine, computed tomography (CT) for better understanding of vertebral anatomy which helps in planning fixation and decompression of canal. Spinal cord compression can be well diagnosed by magnetic resonance imaging. Decompression must be done at the same time wherever necessary. Decompression and stabilization should be done immediately if there is any acute

compression of spinal cord and evolving neurological deficit. Other forms of treatment include de-bulking of spinal tumors and surgical clearance of metastases, which in turn can be achieved by removal of partial or complete vertebra with or without spacer and graft augmentation. Surgery in patients with pathological spinal fractures always give better results; than if treated conservatively. Patient can be treated conservatively only if elderly patients present with multiple spinal secondaries with pathological fracture and other co-morbid factors.

Fig – 8a

Fig – 8b

Fig – 8c

Fig – 8a & 8b, Radiographs of dorso-lumbar spine of a patient showing pathological vertebral body fractures due to metastases from small cell lung carcinoma. Fig – 8c, MRI picture showing spinal cord compression. Fig – 8d & 8e, Post operative radiographs of same patient after canal decompression and posterior stabilization.

Post operative care :

The post operative physical therapy and rehabilitation of patients who underwent surgery for pathological fractures mainly depends up on the intraoperative findings, quality of the bone, stability of the construct and implants used.

The main aim of surgery in pathological fractures is to make the patient independent, to improve the functional quality of life and to bring down the complications associated with prolonged immobility like, deep vein thrombosis, pressure sore and cardio-pulmonary complications.

Compared to general population, these patients after surgery need protected immobilization for longer duration. Static muscle strengthening exercises can be started on the very next day of surgery. For long bone pathological fractures after surgical stabilization, limbs needs to be protected with removable brace for a period of 6 weeks. Gradual assisted weight bearing can be started after 6 weeks.

Deep vein thrombosis prophylaxis is of paramount importance. Chemo-radiation can be used if indicated. Delay in wound healing and wound complications should always be kept in mind before starting post operative chemo-radiation.

MATERIALS AND METHODS:

It is a prospective and retrospective study of functional outcome analysis of surgical stabilization in pathological fractures due to metastases or primary malignant bone tumors, conducted at Institute of Orthopaedics and Traumatology , Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai from june 2012 - december 2015.

Our study consists of 20 patients of pathological fractures who presented to us, due to metastases. Inclusion criteria consists of age more than or equal to 18 years, pathological fractures of long bones and spine secondary to metastases or due primary malignant tumours of bone, where conservative methods failed or was not indicated and patients with minimum expected life span of 6 weeks.

Exclusion criteria are open injuries, terminally ill patients with less average expected life span and medical contra indications for surgery.

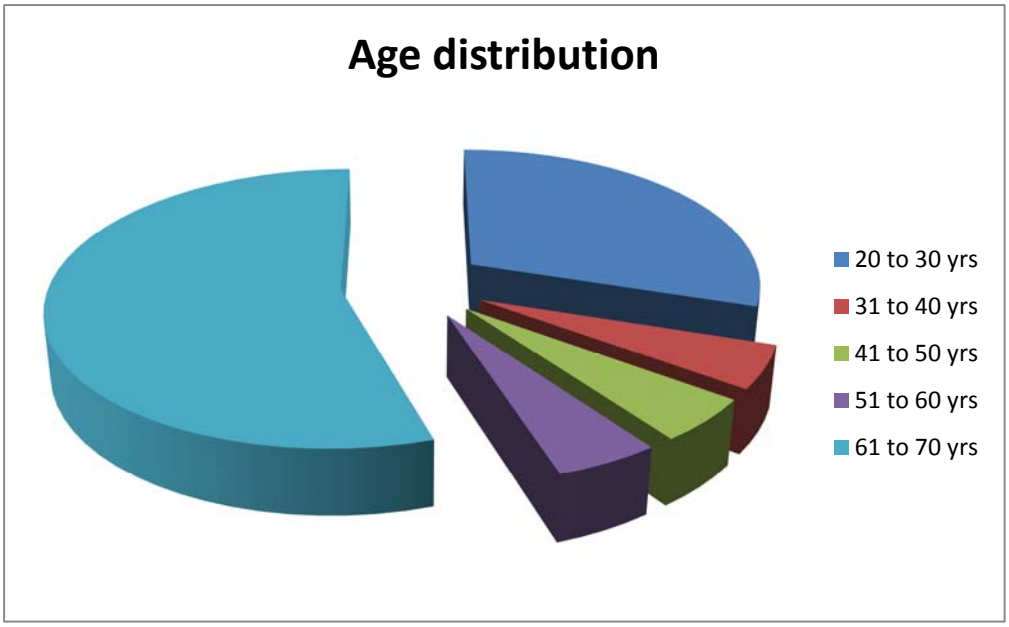
In our study after general resuscitation of the patients, a detailed clinical examination and radiological assessment was done.

Patients were treated with temporary immobilisation initially and were operated between 1 to 2 weeks.

Age incidence and distribution:

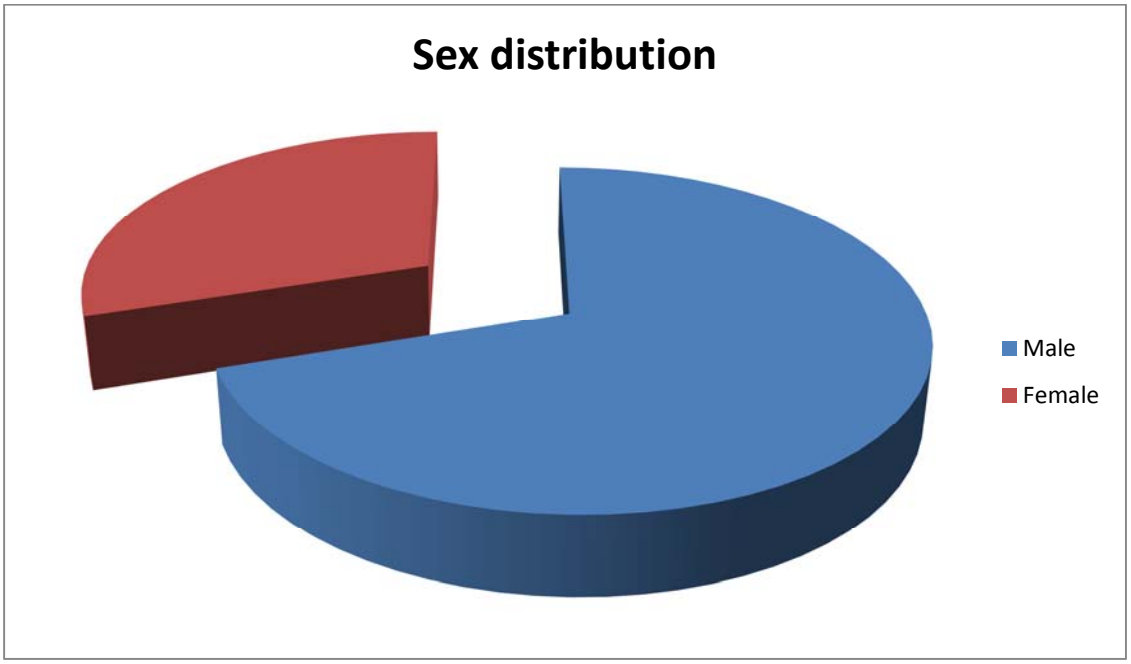
The mean age of the patients in our study is 40 years (20 to 67).

Age	No of Patients	Percentage
20 to 30 Yrs	6	30%
31 to 40 Yrs	1	5%
41 to 50 Yrs	1	5%
51to 60 Yrs	1	5%
61 to 70 Yrs	11	55%



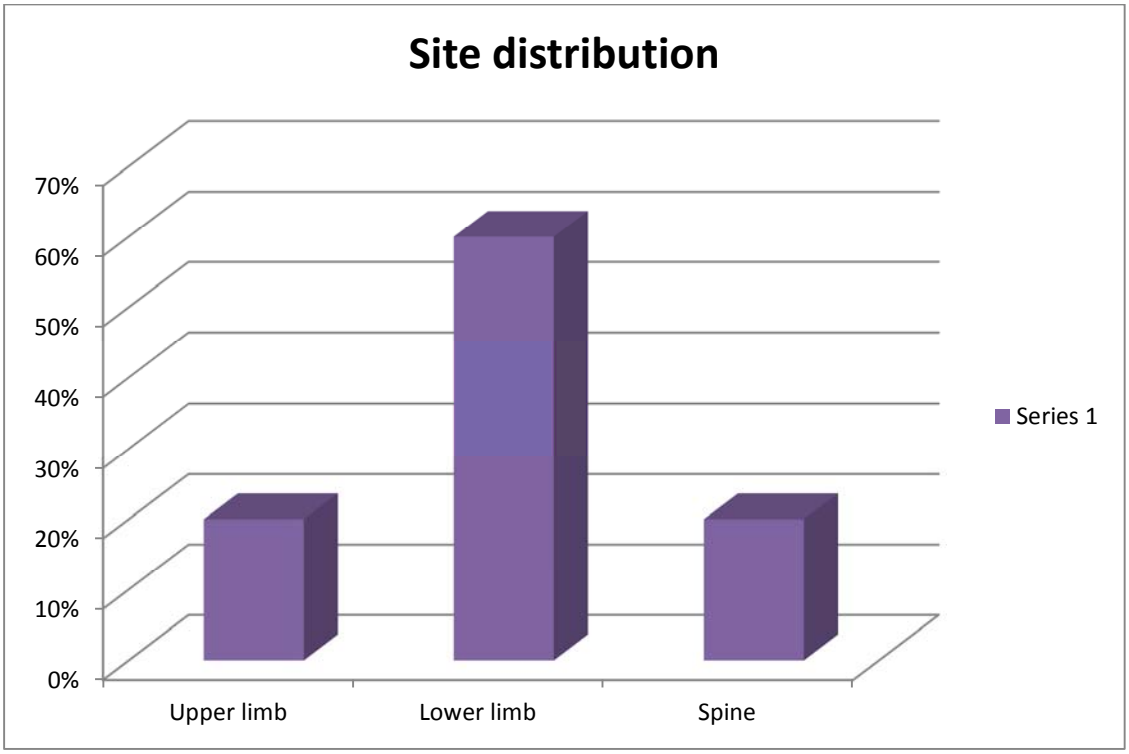
Sex incidence:

Sex	Number of patients	Percentage
Male	14	70%
Female	6	30%



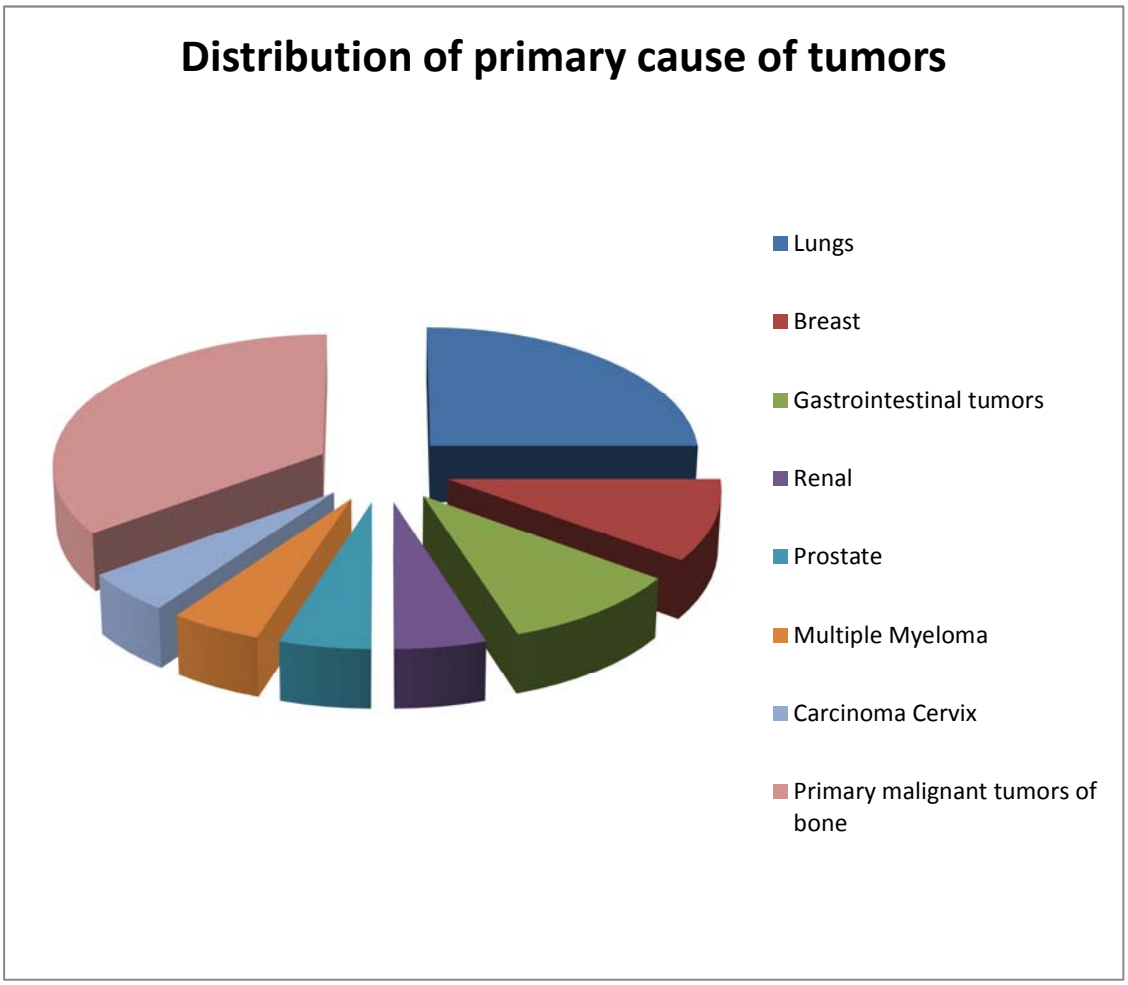
Site distribution:

Site	Number of patients	Percentage
Upper limb	4	20%
Lower limb	12	60%
Spine	4	20%



Primary cause of fractures:

Primary cause	Number of patients	Percentage
Lungs	5	25%
Breast	2	10%
Gastrointestinal tumors	2	10%
Renal	1	5%
Prostate	1	5%
Multiple myeloma	1	5%
Carcinoma cervix	1	5%
Primary malignant tumors of bone	7	35%


Distribution of primary cause of tumors
Lungs
Breast
Gastrointestinal tumors
Renal
Prostate
Multiple Myeloma
Carcinoma Cervix
Primary malignant tumors of bone

Pre operative work up :

As a pre operative workup, all patients with pathological fractures due to both, known or unknown primary cause, underwent a complete skeletal survey or a radionuclide bone scan as an evaluation for occult metastases and to asses the integrity of remaining skeleton. All patients underwent basic blood investigations to confirm skeletal metastasis like serum calcium, alkaline phosphatase, phosphorus, PSA, thyroid profile, urine BJP & serum protein electrophoeresis, and other radiological investigations like USG abdomen, CT chest and CT abdomen and pelvis.

Treatment methods used in our study:

Interlocking intramedullary nailing	4
Plate osteosynthesis	2
DCS	2
Posterior stabilization of spine	4
Arthroplasty	2
Tumor resection custom made mega prosthesis fixation	6

Post operative management and follow up:

Routine antibiotics were administered for 5 to 7 days, the drain from surgical site was removed after 48 hours and wound was examined.

For all the patients with pathological fractures limb was protected in initial post operative days with plaster of paris application or a removable brace in case of pathological fractures of spine for six weeks with intermittent gentle passive mobilization under supervision. After 6 weeks, brace was removed and full mobilization was started with gradual weight bearing depending upon the patient's general condition and intra operative findings.

For all pathological spine fractures, early post operative immobilization was done in the form of removable brace for 6 weeks and gradual mobilization was started under strict supervision, gradual weight bearing advised depending up on patient's neurological status, general condition and intra operative findings.

Patients received post operative chemo radiation depending on sensitivity of the primary disease.

Functional outcome in these patients have been assessed using standard scale proposed by Musculo Skeletal Tumor Society, which is having two versions of scale, 1987 and 1993 versions.

The MSTS forms were introduced as a standard analysis tool to asses and analyse the functional outcome in patients who underwent surgical stabilization for pathological fractures.

The 1987 version of this score chart concentrates mainly on the clinical outcome parameters; mainly pain, movements, stability, power, deformity, functional activity and emotional acceptance. Whereas the other version of it, i.e 1993 concentrates mainly at the functional parameters like gait, walking, hand positioning, dexterity and lifting ability. Final score may be average numerical value or its percentage.

All the patients were followed up with radiographs of involved parts at serial intervals and evaluated for metastases to other regions of the body and treated accordingly.

Description of MSTS score chart used for functional outcome analysis in surgically treated pathological fractures:

For upper limb pathological fractures:

1.Pain score		
Description	Data	Numerical value
Relieved of pain	Without medication	5
Intermediate		4
Non disabling pain	NSAIDS	3
Intermediate		2
Disabling pain for some time of the day	Narcotics – whenever needed	1
Disabling pain – always	Narcotics – always	0

2.Function		
Description	Data	Numerical value
No restriction of functions	Functionally stable	5
Intermediate		4
Lack of interest / Anhedonia	Mild disability	3
Intermediate		2
Difficulty in attending job	Moderate disabity	1
Not able to do day today activities	Complete disability	0

3. Emotional status		
Description	Data	Numerical value
Enthusiastic	Would advice others to go for it	5
Intermediate		4
Happy at self	Would like to repeat	3
Intermediate		2
Agree	Would repeat with out of interest	1
Not liking it anymore	Avoiding	0

4.Hand positioning		
Description	Data	Numerical value
Unlimited	180^{o} elevation	5
Intermediate		4
Not above shoulder	90^{o} elevation	3
Intermediate		2
Not above waist	30^{o} elevation	1
None	0^{o} elevation	0

5.Manual dexterity		
Description	Data	Numerical value
No limitations	Normal dexterity and sensation	5
Intermediate		4
Loss of fine movements	Can’t button and unbutton shirt, mild loss of sensation	3
Intermediate		2
Can’t pinch	Major loss of sensation	1
Can’t grasp	Anaesthetic hand	0

6. Lifting ability		
Description	Data	Numerical value
Normal	Matches normal	5
Intermediate	Mild limitation	4
Limited	Minor load	3
intermediate	Gravity only	2
Helping only	Can’t overcome gravity	1
Can’t help	Can’t move	0

For lower limb pathological fractures:

1. Pain score		
Description	Data	Numerical value
Relieved of pain	Without medication	5
Intermediate		4
Non disabling pain	NSAIDS	3
Intermediate		2
Disabling pain for some time of the day	Narcotics – whenever need	1
Disabling pain – always	Narcotics – always	0

2.Function		
Description	Data	Numerical value
No restriction of functions	Functionally stable	5
Intermediate		4
Lack of interest / Anhedonia	Mild disability	3
Intermediate		2
Difficulty in attending job	Moderate disabity	1
Not able to do day today activities	Complete disability	0

3. Emotional status		
Description	Data	Numerical value
Enthusiastic	Would advice others to go for it	5
Intermediate		4
Happy at self	Would like to repeat	3
Intermediate		2
Agree	Would repeat with out of interest	1
Not liking it anymore	Avoiding	0

4.Walking ability		
Description	Data	Numerical value
Near normal ability	Comparable to status before trauma	5
Intermediate		4
Able to make out for shopping	With minor difficulties	3
Intermediate		2
Manage to walk at home only	With major difficulties / with support	1
Cannot walk on own	Need support – assistance or Wheelchair	0

5. Gait		
Description	Data	Numerical value
Normal	Comparable to status before trauma	5
Intermediate		4
Minimum cosmetic intolerance	Cosmetic alteration	3
Intermediate		2
Cosmetic intolerance	With minimum functional compromise	1
Handicap	With gross functional impairment	0

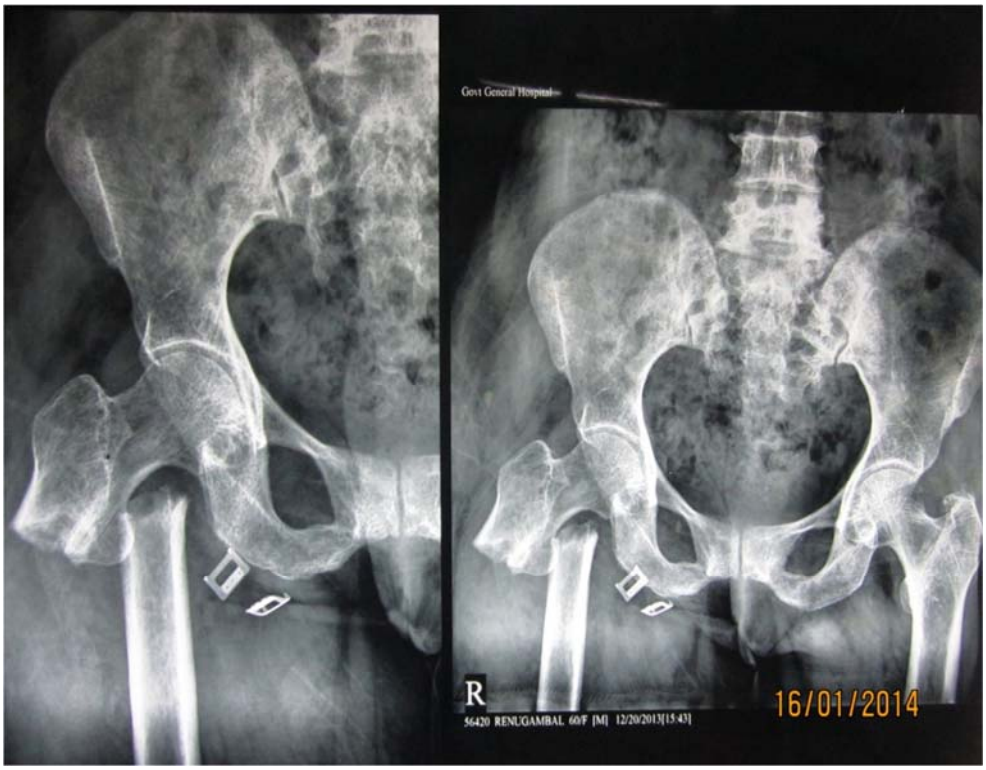
6.Support		
Description	Data	Numerical value
Without any support	Comparable to status before trauma	5
Intermediate	With occasional brace support	4
With removable brace	Brace support for most of the time	3
Intermediate	Occasional	2
cane / crutch	Sometime	1
Cane on both sides / crutches	Always	0

Score analysis for each patient:

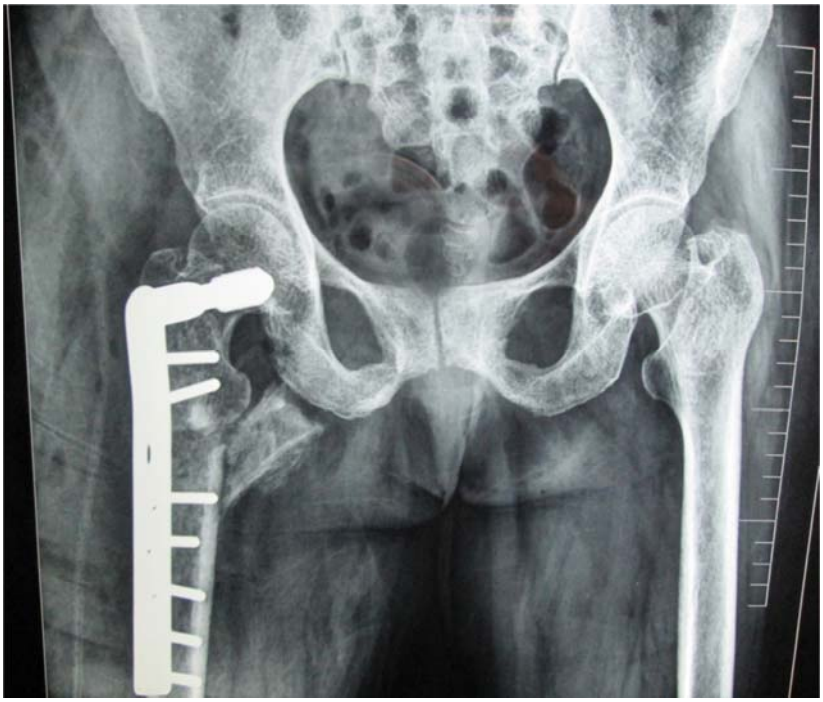
- Total score for upper limb - 30 (normal)
- Total score for lower limb - 30 (normal)
- Excellent outcome – 25 to 30
- Good outcome – 20 to 25
- Poor outcome – less than 20

CASES

Case 1: 60 year old female with pathological subtrochanteric fracture right femur due to metastasis from adenocarcinoma colon managed with open reduction and internal fixation with DCS.



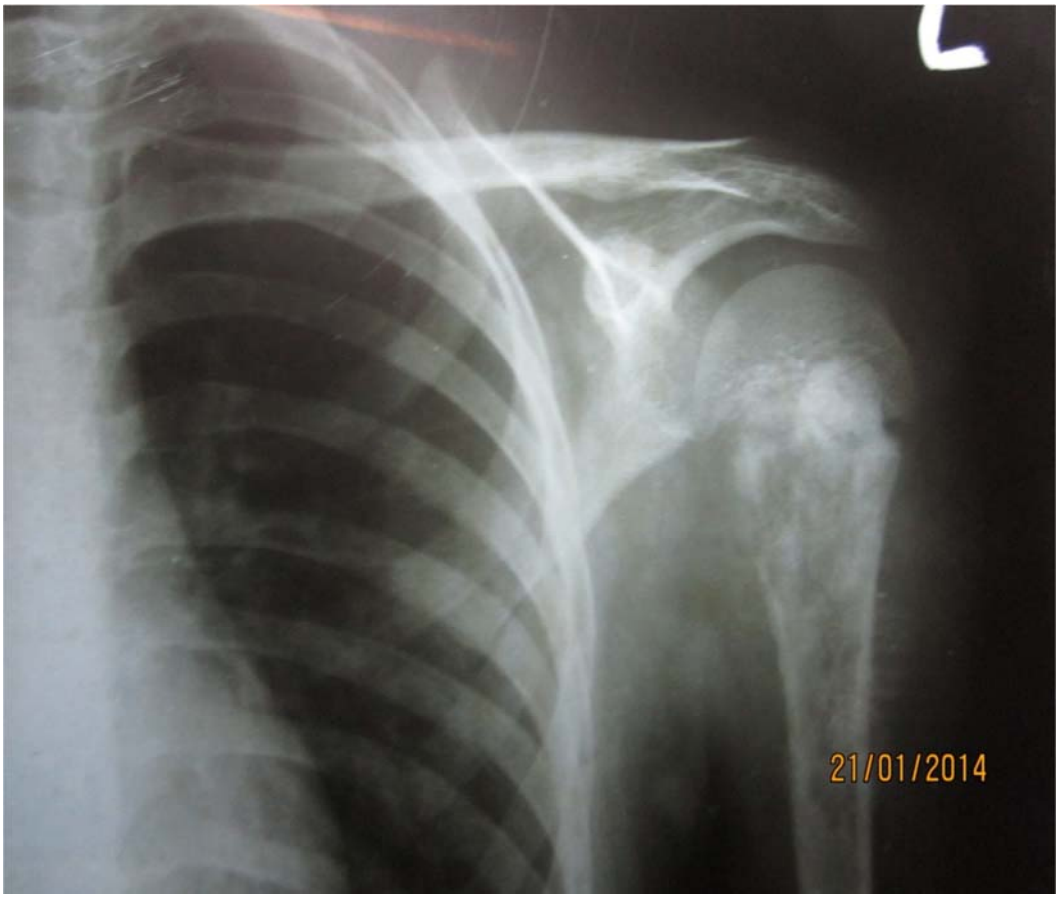
Pre operative



Immediate post operative

12 months post op

Case 2: 14 year old male with pathological fracture left proximal humerus due to osteosarcoma (biopsy proven) managed with tumour clearance by excision and proximal humeral custom made mega prosthesis fixation.



Pre operative

Pre operative

Post operative

1 months post op

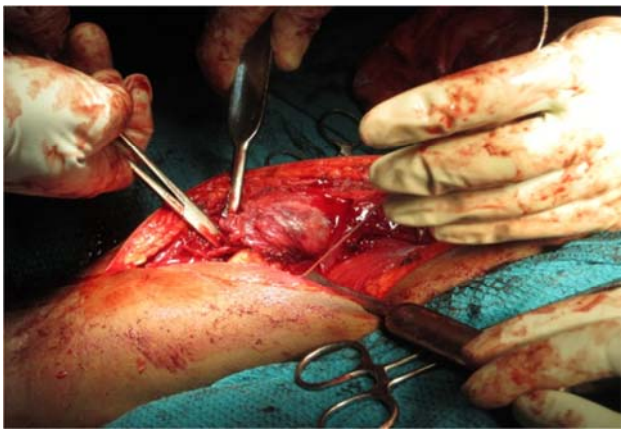
3 months post op

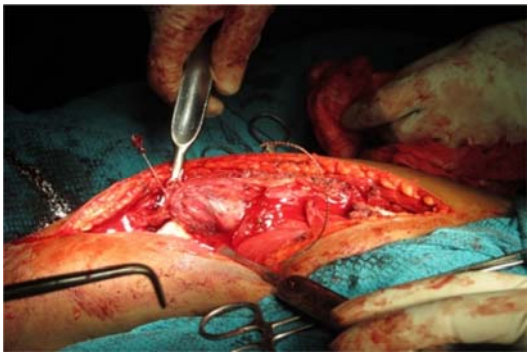
12 months post op

Case 3 - 26 year old male with pathological fracture right shaft of humerus . He had undergone left hip disarticulation for primary rhabdomyosarcoma of left thigh at the age of 24. Managed with metastatic segment excision and fracture site stabilized with plate osteosynthesis.

Pre operative X ray

Clinical picture showing that he underwent left hip disarticulation for primary rhabdomyosarcoma of left thigh at the age of 24.





Intra operative pictures showing excision of metastatic segment and giving tumor clearance.

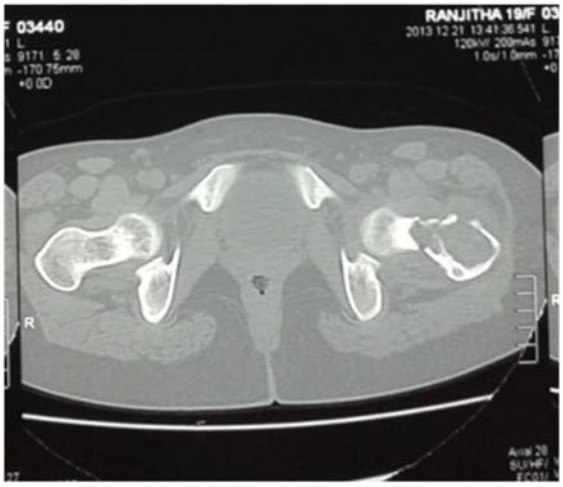
Immediate post operative x ray **At 3 months follow up**

a

At 9 months follow up

Case 4- 16 year old female patient presents with pathological neck of femur fracture with giant cell tumour (biopsy proven) of left proximal femur managed with tumour clearance by excision and proximal femoral custom made mega prosthesis fixation.

Pre operative X ray



Pre operative CT scan

Post operative

Three months follow up

Six months follow up.

One year follow up.

Clinical pictures of the patient

DISCUSSION

As the metastatic process and pathological fractures is an advanced stage and frequently an end stage of a malignant disease with relatively poor prognosis, it is difficult to evaluate the functional outcome in these patients.

The incidence of pathological fractures is estimated to be approximately 10% of all metastases. In our study it is observed that male sex predominates female. Of all the causes bronchial carcinoma as a primary stands with 25%, next is breast carcinoma 10% , gastrointestinal tumors 10% and primary malignant bone tumors is 35%.

Pathological fractures due to metastatic deposits often heralds the end stage of any tumor disease and it indicates that disease is in its end stage. The established primary disease is the cause of death ultimately in majority of the patients. So an estimated average life span of these patients and proper patient counseling is necessary before

planning for any operative procedure. As we look in our data, one year survival rate of 70% is significantly higher when compared to other previous studies. A Swedish study on 192 patients of pathological fractures treated surgically showed average survival rate of 30% for two year follow up. Furthermore, Bohm in his study on a series of 96 patients of pathological fractures who underwent surgical stabilization, reported an average of 54% of survival rate for two year follow up. It is documented that even a better survival rate can be achieved by stabilizing the metastatic lesions with impending pathological fractures prophylactically rather than treating them after established fractures. In addition, the survival differences may also be affected by the different stages of metastatic disease, age and general condition of the patient. 40% of patients in our study had pathological fractures before the detection of primary, disease which was responsible for the fracture. Also these patients presented to us in a well advanced phase of disease without any oncological intervention. Even though it is not statistically significant, functional outcome in patients who underwent

surgery for upper limb pathological fractures is better than those of lower limb and spine fractures. Because of varied distribution of metastatic foci, different age groups, involvement of patients with pathological fractures due to primary malignant tumors of bones and shorter follow up period of about 1 year; calculated survival rate may vary with other studies and accurately measuring the survival rate is not feasible. Even with an expected period of survival for more than six months by treating surgeon and oncologist, 20% of our study group patients succumb to the disease before 6 months. Few patients were lost to follow up and they belonged to sicker sub group. Still higher rate of survival in our study may be because of improvement in the current diagnostic modalities, established intensive care, oncological therapy and surgical techniques.

However functional outcome analysis which is the goal of our study gives a relatively better results in the average follow up of one year, which has been calculated using musculo-skeletal tumor society

(MSTS) score for analysis of functional outcome in surgically treated patients with pathological fractures.

We had a relative lower rate of intra operative complications such as bleeding, systemic embolism and periprosthetic fractures. A study by Wedin in 1998 on a series of 102 patients showed a much higher complication rate of 4.1%. Post operative wound infection was noted in a patient of pathological vertebral fracture treated with posterior stabilization, which subsided after wound wash and appropriate antibiotic therapy according to wound discharge culture and sensitivity.

At 6 weeks postoperative follow up, pain was modest and tolerable without analgesics, ambulation with a cane support was possible which allowed patients to walk around at their home. Our study showed a much better pain control at 6 weeks post operative period, which was documented using MSTS pain scale. It also shows a significant improvement in functional outcome as well, which is indicated on MSTS charts.

The average time of improvement in functional status is really important in these patients, which was reported to be minimum of 6 weeks in our study. Though our study supports the criteria given by Parrish and Murray, that minimum of 6 weeks of life expectancy is necessary to consider for surgery, however it is practically possible that surgery may benefit even those patients with shorter life expectancy.

It was a practical difficulty to conclude the optimal method of treatment for pathological fractures because of relatively small number of patients and wide range of subject selection with different pathology.

However, early improvement in functional status, better pain control and relatively much lesser complication rate in our study, strongly recommends surgical stabilization for pathological fractures.

RESULTS

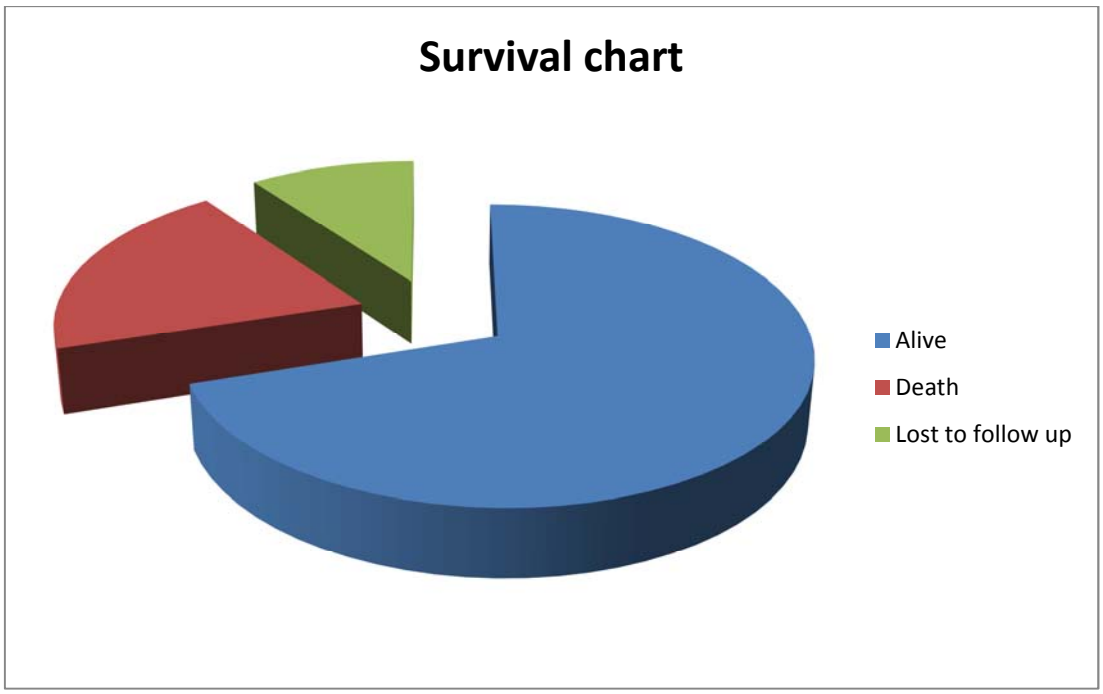
Results of our study have been elaborated under

- Survival
- Pain relief
- Ambulation
- Functional score chart
- Complications

Survival

The overall survival rate of our study is 70% at one year follow up. Even with an expected survival period of more than six months by treating surgeon and oncologist, 20% of our study group patients succumbed to the disease before 6 months. 2 patients were lost to follow up at 8 months and these patients were a part of sicker subgroup.

Fourteen patients are still alive and doing well at the end of one year follow up.



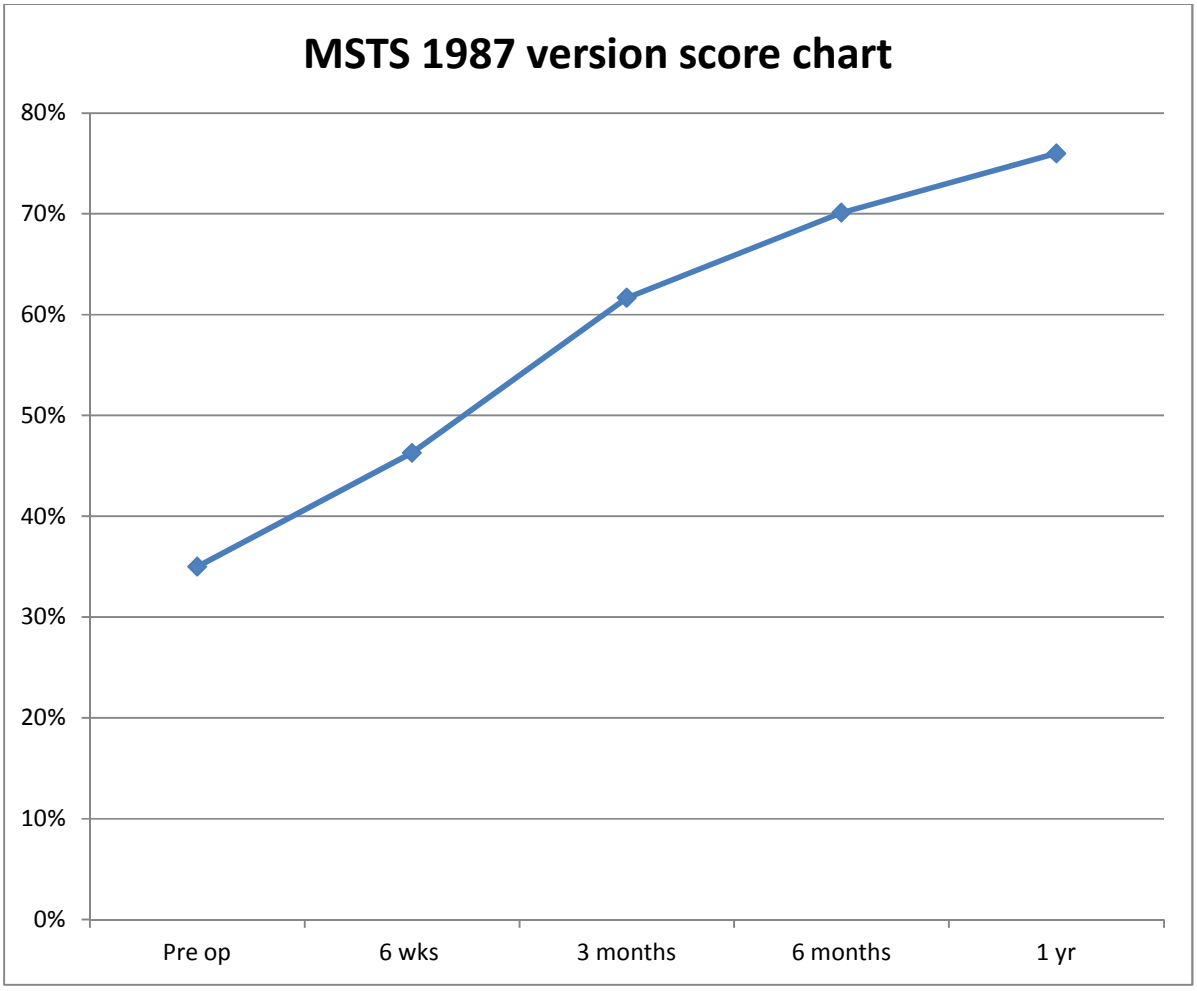
Pain relief

There is an significant improvement in pain over time in our study. Minimum time period recorded was 6 weeks. Gradual increase in the score is recorded by using MSTS pain scale. All patients who underwent treatment for pathological fractures suffered pain at the fracture site, majority of our patients also had pain due to primary disease or tumors, requiring analgesics therapy sometimes narcotics

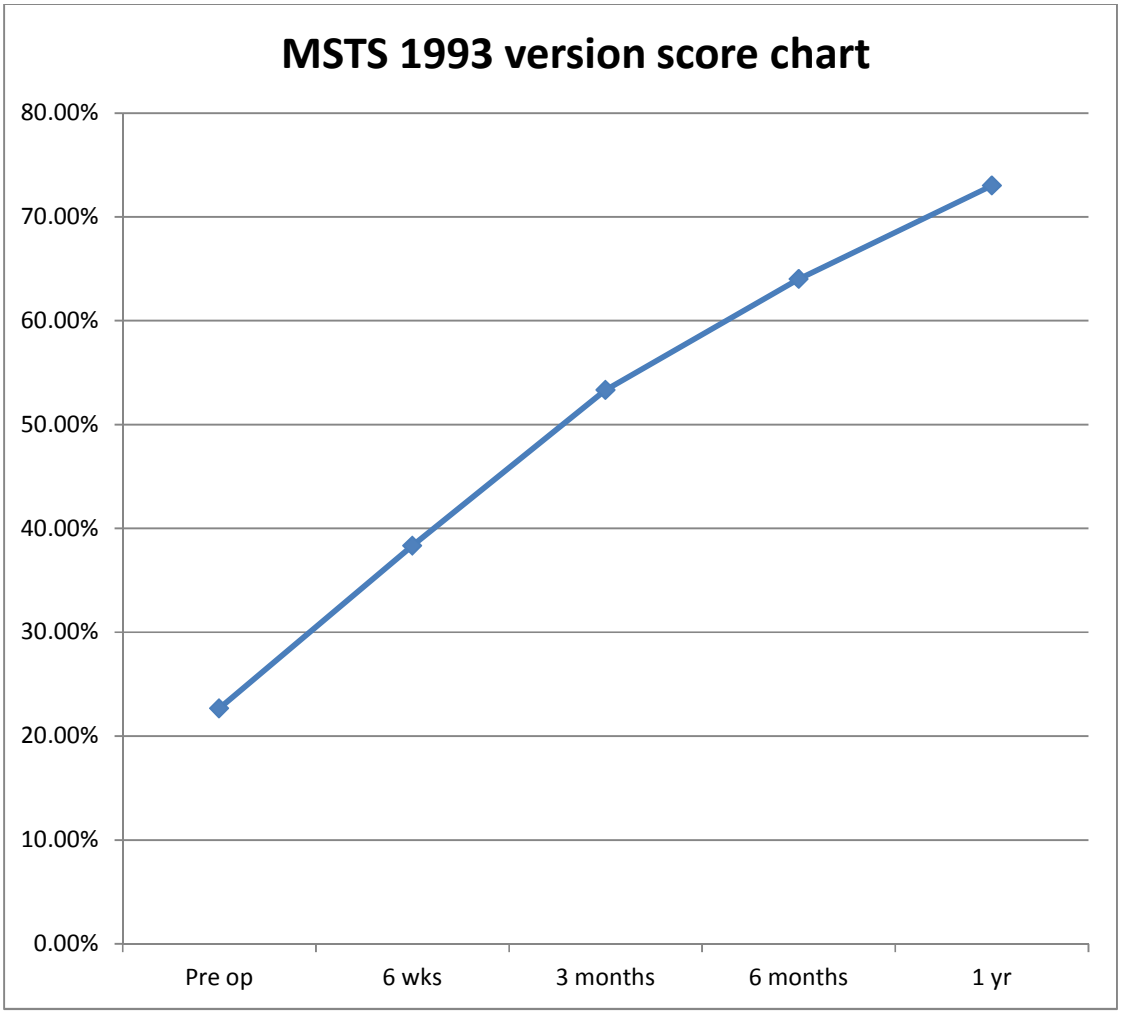
too when common analgesics failed to control pain. MSTS scores for serial follow up has been tabulated below.

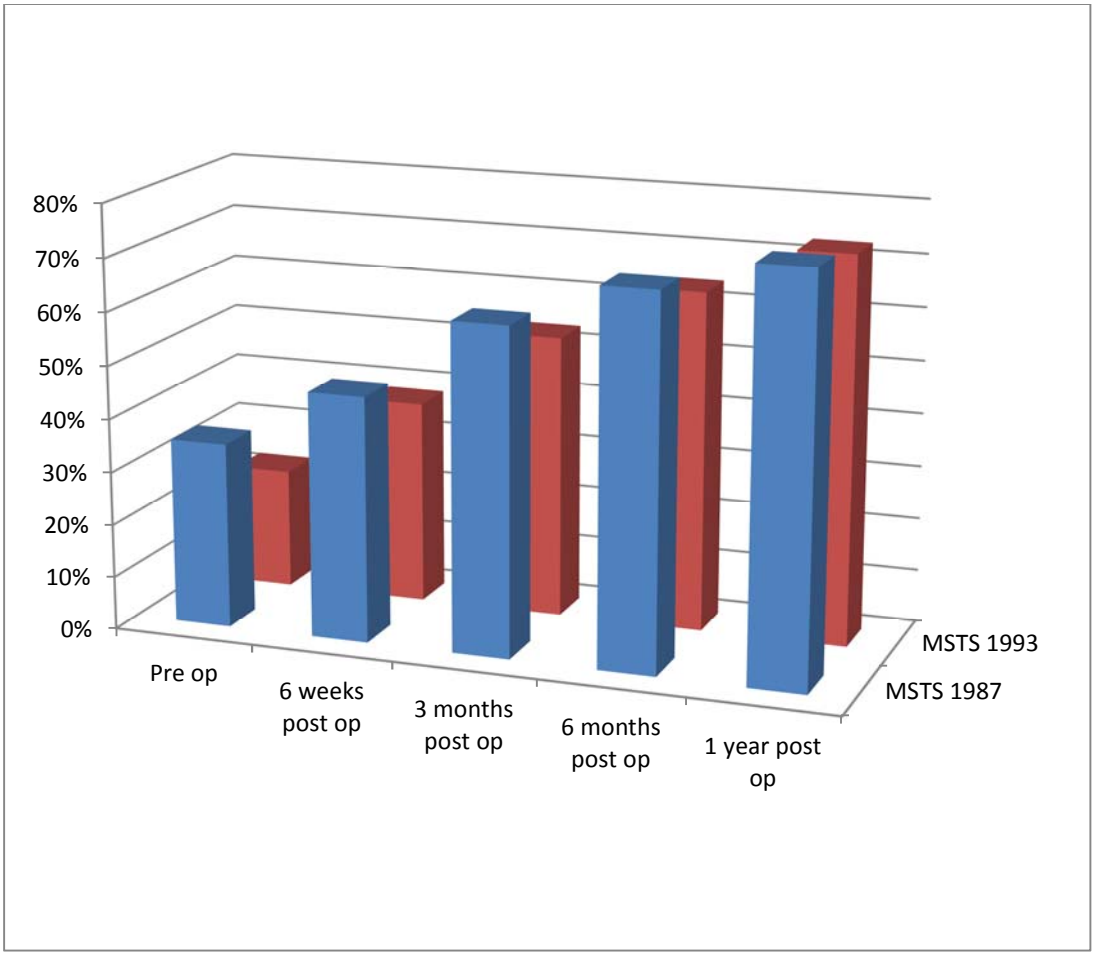
Functional score charts:

MSTS 1987 version	**Pre operative**	**Six weeks**	**3 months**	**6 months**	**1 year**
Pain	2.4	3.2	3.9	4	4.2
Stability	0.6	2.2	2.8	3	3.2
Deformity	4.0	3.2	4	4.2	4.2
Strength	2	2.1	2.8	3	3.2
Functional activity	1	1.2	2	3	4
Emotional acceptance	0.5	2	3	4	4


MSTS 1987 version score chart
80%
70%
60%
50%
40%
30%
20%
10%
0%
Pre op
6 wks
3 months
6 months
1 yr

MSTS 1993 version	**Preoperative**	**Six weeks**	**3 months**	**6 months**	**1 year**
Pain	1.3	2	3	3.2	4
Function	1	1.5	2	3	3.5
Walking aids/ hand positioning	1.5	2	2.5	3	3.2
Gait	1.5	2	3	3	3.2
Walking / lifting	1	1.5	2.5	3	4
Emotional acceptance	0.5	2.5	3	4	4


MSTS 1993 version score chart
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
Pre op
6 wks
3 months
6 months
1 yr


80%
70%
60%
50%
40%
30%
20%
10%
0%
Pre op
6 weeks post op
3 months post op
6 months post op
1 year post op
MSTS 1993
MSTS 1987

Ambulation

Following surgery, all patients treated for lower limb pathological fractures were advised strict non weight bearing for 6 weeks, during this period limbs were protected in a removable brace. Static muscle strengthening exercises were started on the very next day of surgery under the supervision of physiotherapist. Patients were allowed to bear weight only after six weeks and radiological evidence of fracture healing, depending on the patient general condition and intra-operative findings.

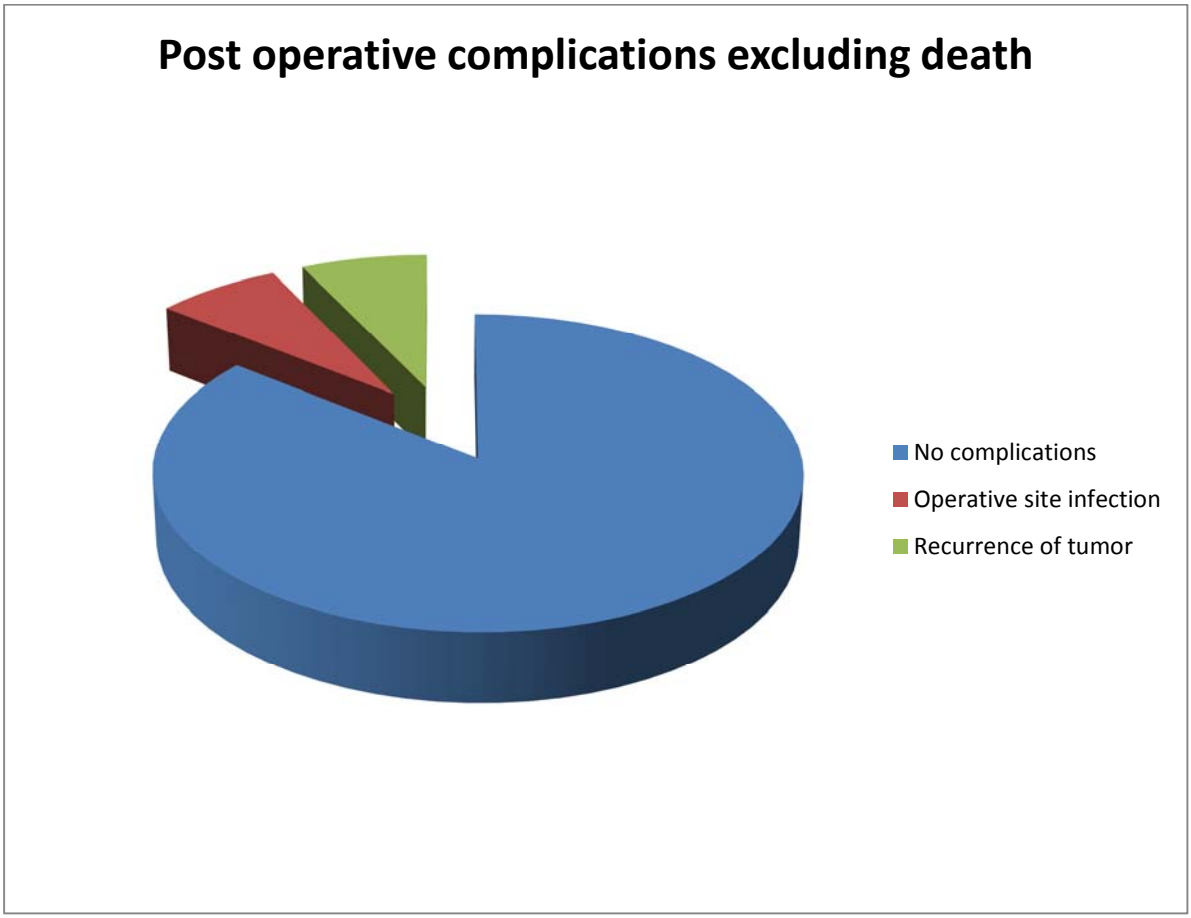
All patients of surgically treated upper limb pathological fractures were put on upper limb static and dynamic muscle strengthening exercises from the third post operatative day. Most of the patients regained strength, relative stability and at least an average use of limb by the day of discharge.

Spine patients who underwent posterior stabilization were kept under protected immobilization with removable brace till they were

relieved of operative site pain. Limb physiotherapy and muscle strengthening exercises were started on the very next day after surgery under supervision of a physiotherapist. Gradual weight bearing with support was started depending upon their neurological improvement & intra-operative findings.

Complications

Operative site infection was noted in one patient of spine fracture managed with posterior stabilization, which subsided after wound wash and administration appropriate antibiotics. Recurrence of tumor was found in one patient of osteosarcoma of distal femur with pathological fracture, who was initially treated with surgical clearance of tumor and custom made mega prosthesis fixation. This patient underwent above knee amputation. At 3 months follow up, stump was healthy and patient started walking with the help of prosthetic fit to his stump.


Post operative complications excluding death
No complications
Operative site infection
Recurrence of tumor

The following are the statistical analysis of various data and their significance in our study:

Table 1. Age distribution v/s sex:

Age	Male		Female		Total	
	N	%	N	%	N	%
20 to 30 Yrs.	4	28.57	2	33.33	6	30
31 to 40 Yrs.	0	0	1	16.67	1	5
41 to 50 Yrs.	1	7.14	0	0	1	5
51to 60 Yrs.	4	28.57	2	33.33	6	30
61 to 70 Yrs.	5	35.72	1	16.67	6	30
TOTAL	**14**	**100**	**6**	**100**	**20**	**100**
Chi-square Value	**3.33**					
p-value	**0.50**					
Significant	**Not Significant**					

Age	Male	Female	Total
Mean	44.93	44.50	48.30
sd	18.18	21.85	18.93
Chisqure Value	**0.58**		
p-value	**0.57**		
Significant	**Not Significant**		

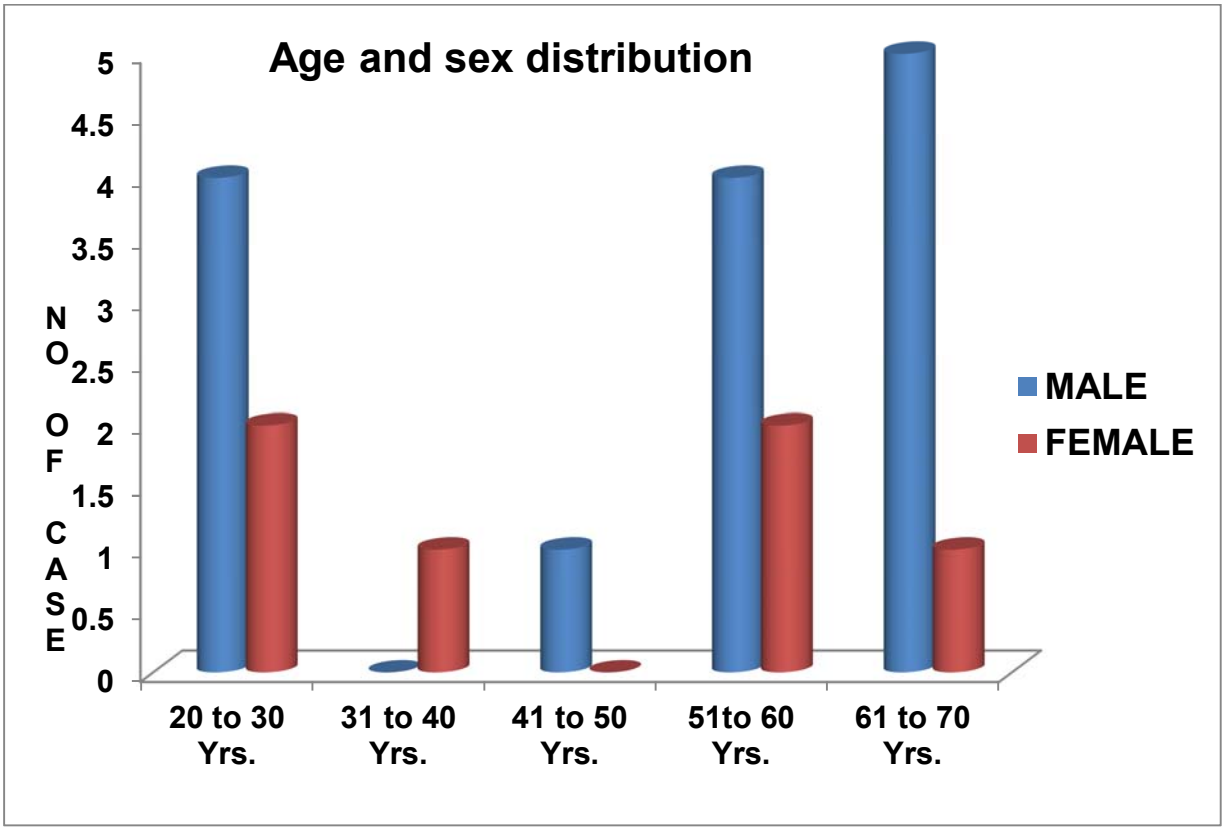


Table 2. Mode of injury v/s sex:

Age	Male		Female		Total	
	N	%	N	%	N	%
Self-fall at home	7	58.34	3	50.00	10	55.56
Back Pain	1	8.33	2	33.33	3	16.66
Chronic swelling and pain in limb	1	8.33	0	0	1	5.56
Fall from two wheeler/ height	3	25.00	1	16.67	4	22.22
TOTAL	**12**	**100**	**6**	**100**	**18**	**100**
Chi-square Value	**2.18**					
p-value	**0.54**					
Significant	**Not Significant**					

Table 3. Primary cause v/s time delay in surgery:

Primary Cause	N	Time Delay	
		Mean	Sd
Lungs	5	27.40	20.28
Breast	2	20.50	0.71
Gastrointestinal tumors	2	15.00	0.00
Renal	1	15.00	0.00
Multiple myeloma	1	40.00	0.00
Carcinoma cervix	1	10.00	0.00
Primary malignant tumors of bone	7	24.00	18.89
F-value*	0.40		
P-Value	0.86		
Significant	Not Significant		

***Analysis of Variance (ANNOVA)**

Table 4. Procedure done v/s time delay in surgery:

Procedure done	N	Time Delay	
		Mean	Sd
Interlocking intramedullary nailing	4	26.75	23.36
Plate osteosynthesis	2	27.50	17.68
DCS	2	15.00	0.00
Posterior stabilization of spine	4	20.25	8.18
Arthroplasty	2	14.50	0.71
Tumor resection custom made mega prosthesis fixation	5	2.21	21.73
F-value *	0.33		
P-Value	0.89		
Significant	Not Significant		

***Analysis of Variance (ANNOVA)**

Table 5. Primary cause v/s surgical time:

Primary Cause	N	Surgical Time	
		Mean	sd
Lungs	5	70.00	34.64
Breast	2	90.00	14.14
Gastrointestinal tumors	2	75.00	21.21
Renal	1	120.00	
Prostate	1	160.00	
Multiple myeloma	1	120.00	
Carcinoma cervix	1	60.00	
Primary malignant tumors of bone	7	125.71	35.90
F-value *	2.15		
P-Value	0.12		
Significant	Not Significant		

***Analysis of Variance (ANNOVA)**

Table 6. Procedure done v/s surgical time:

Procedure done	N	Surgical time	
		Mean	Sd
Interlocking intramedullary nailing	4	72.50	39.48
Plate osteosynthesis	2	120.00	0.00
DCS	2	90.00	42.43
Posterior stabilization of spine	4	82.50	17.08
Arthroplasty	2	60.00	0.00
Tumor resection custom made mega prosthesis fixation	6	143.33	23.38
F-value *	5.47		
P-Value	0.01		
Significant	Significant		

***Analysis of Variance (ANNOVA)**

Table 7. Procedure done v/s complications:

Procedure	Complications					
	No complication	Post op infection	Recurrence	Death	Total	%
Interlocking intramedullary nailing	3	0	0	1	4	20.00
Plate osteosynthesis	1	0	0	1	2	10.00
DCS	2	0	0	0	2	10.00
Posterior stabilization of spine	1	1	0	2	4	20.00
Arthroplasty	2	0	0	0	2	10.00
Tumor resection custom made mega prosthesis fixation	5	0	1	0	6	30.00
TOTAL	14	1	1	4	20	100
%	70.00	5.00	5.00	20.00	100	
Chi square	**13.04**					
p-value	**0.60**					
Significant	**Not Significant**					

Table 8. Primary cause v/s complications:

Primary Cause	Complications					
	No complication	Post op infection	Recurrence	Death	Total	%
Lungs	3	1	0	1	5	25.00
Breast	0	0	0	2	2	10.00
Gastrointestinal tumors	2	0	0	0	2	10.00
Renal	1	0	0	0	1	5.00
Prostate	1	0	0	0	1	5.00
Multiple myeloma	0	0	0	1	1	5.00
Carcinoma cervix	1	0	0	0	1	5.00
Primary malignant tumors of bone	6	0	1	0	7	35.00
TOTAL	14	1	1	4	20	100
%	70.00	5.00	5.00	20.00	100	
Chi square	19.92					
p-value	0.53					
Significant	Not Significant					

Table 9. Pre operative MSTS score:

Pre OP MSTS Score	N	%
< 1	5	25.00
1 – 2	13	65.00
≥ 2	2	10.00
TOTAL	20	100
Mean ± sd	1.15 ± 0.36	
Range	0.80 – 2.00	

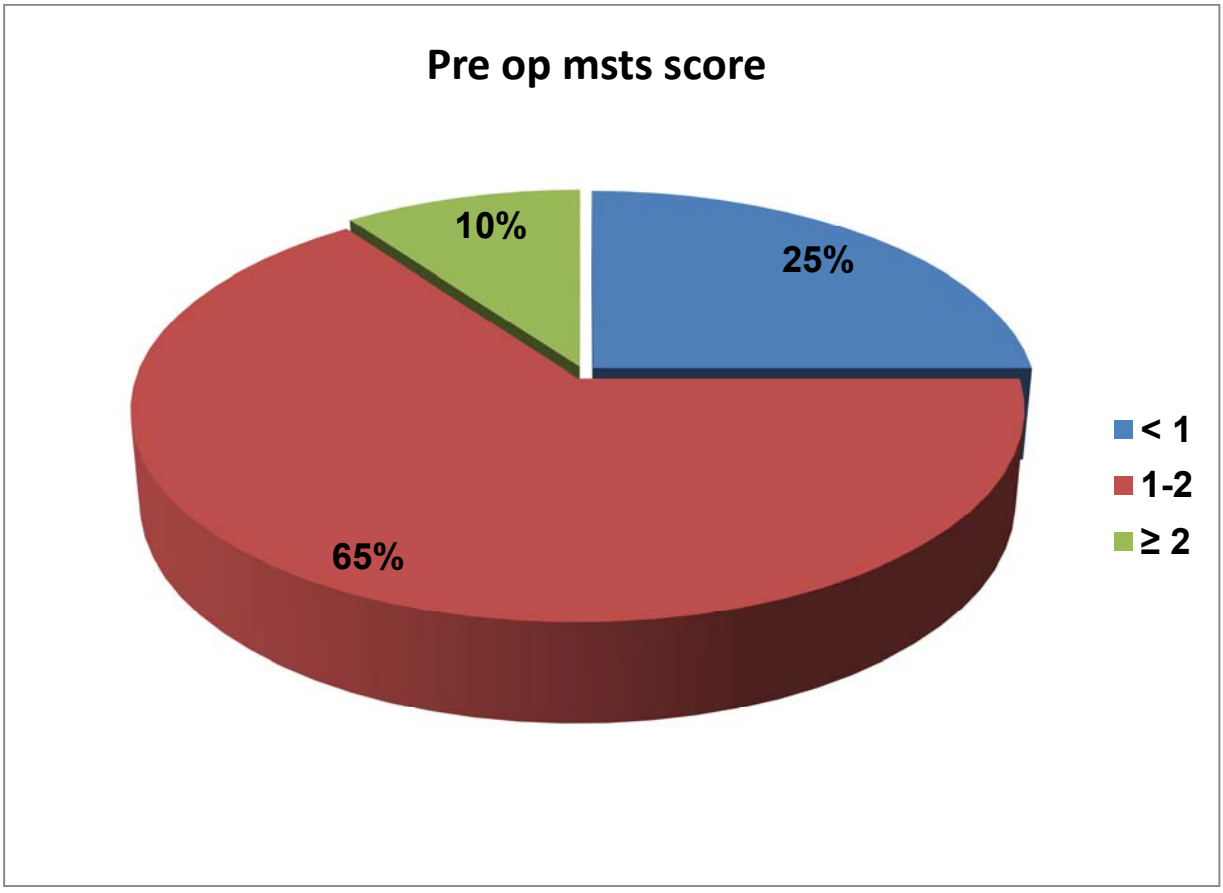


Table 10. Post operative MSTS score:

Post OP MSTS Score	N	%
2 - 3	4	25.00
3 - 4	6	37.50
4 - 5	10	62.50
TOTAL	16	100
Mean ± sd	3.70 ± 0.94	
Range	2.00 – 5.00	

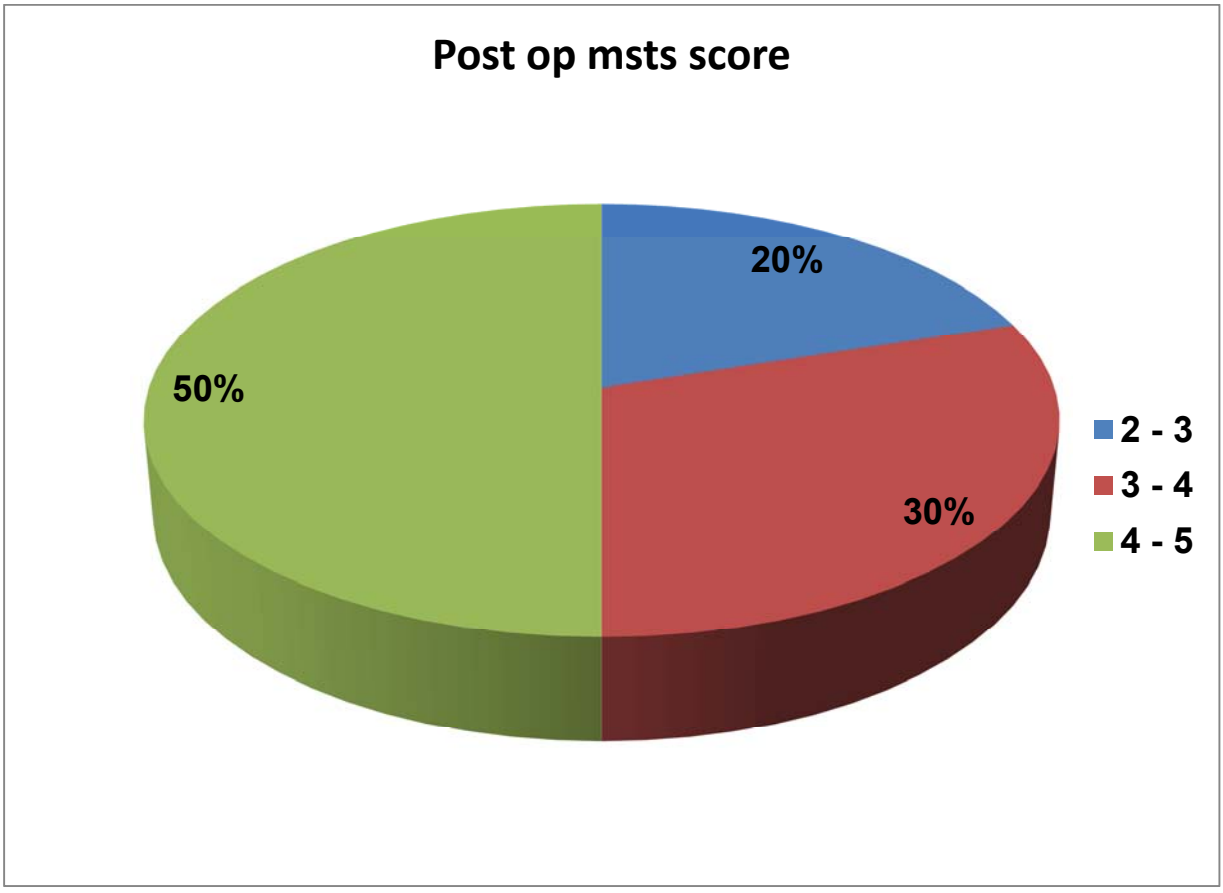


Table 11. Follow up status:

Follow-up	N	%
2 Months	2	11.11
3 Months	1	5.56
4 Months	1	5.56
5 Months	2	11.11
6 Months	7	38.88
7 Months	1	5.56
12 Months	2	11.11
Follow up Lost	2	11.11
TOTAL	18	100

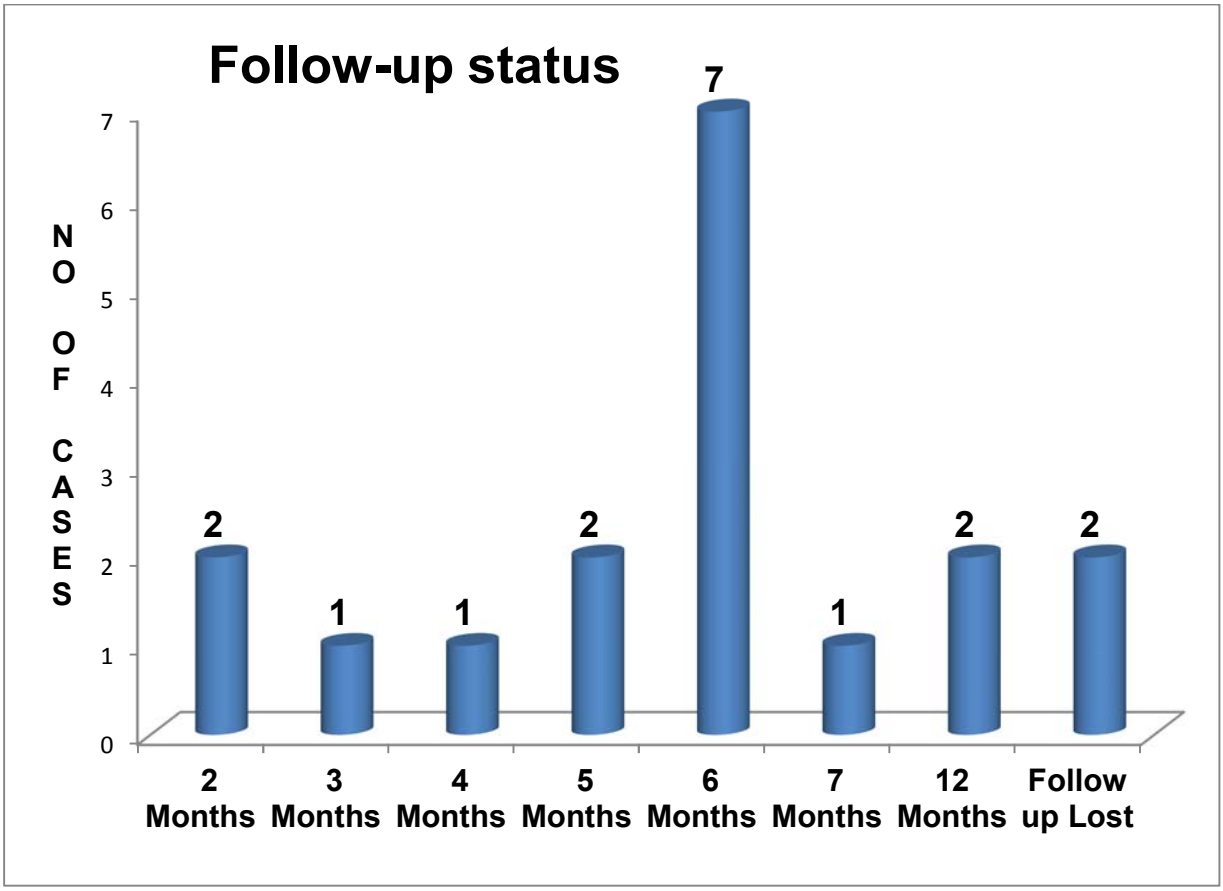


Table 12. Pre operative MSTS score v/s results:

Pre OP MSTS Score	Outcome (result)			Total
	Poor	Good	Excellent	
< 1	2	1	0	3
1 – 2	2	8	1	11
≥ 2	0	2	0	2
TOTAL	4	11	1	16
Chi square	4.10			
p-value	0.39			
Significant	Not Significant			

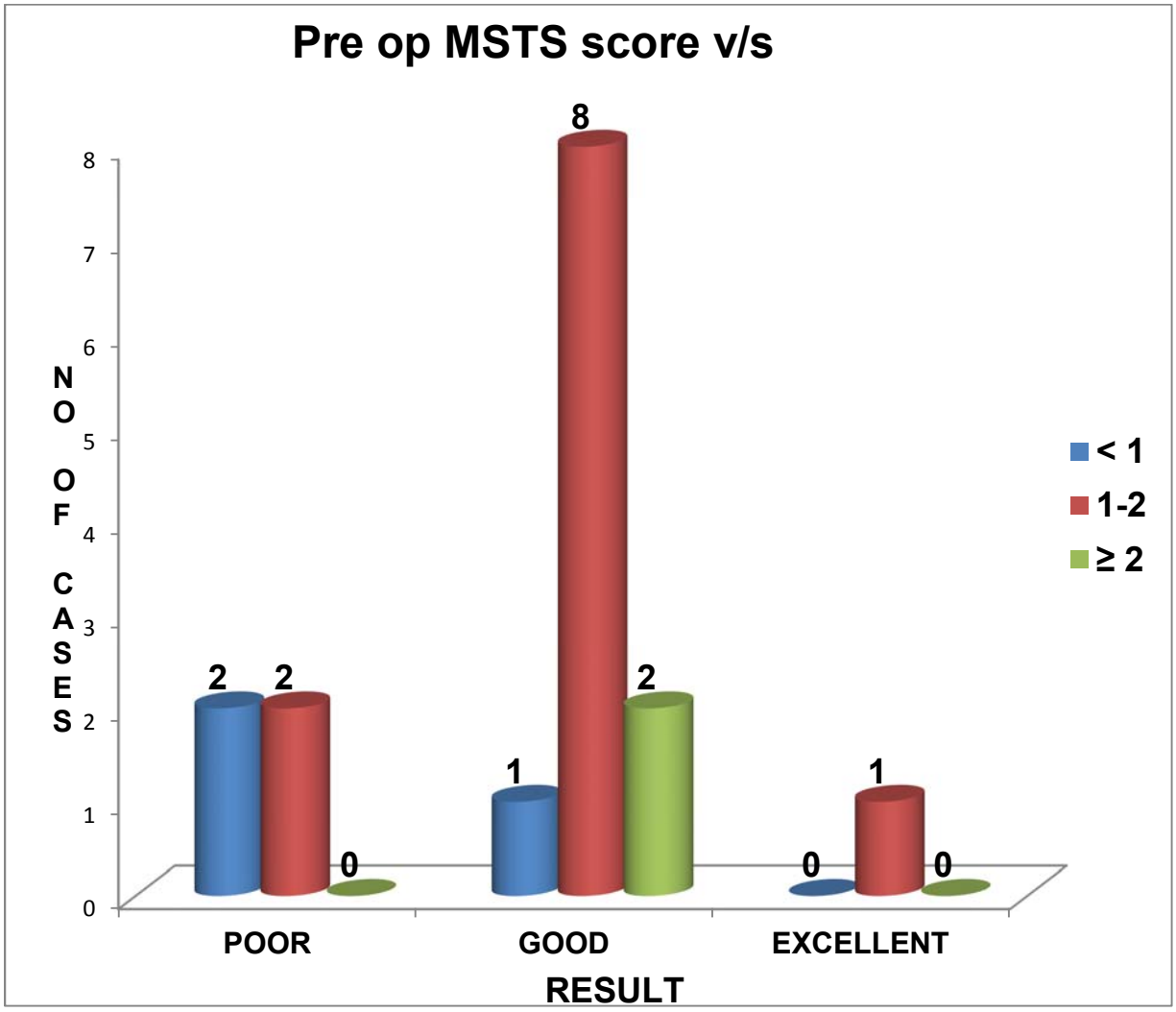


Table 13. Post operative MSTS score v/s results:

	Outcome (result)			
Pre OP MSTS Score	Poor	Good	Excellent	Total
2 - 3	3	0	0	3
3 - 4	1	2	0	3
4 - 5	0	9	1	10
TOTAL	4	11	1	16
Chi square	12.66			
p-value	0.01			
Significant	Significant			

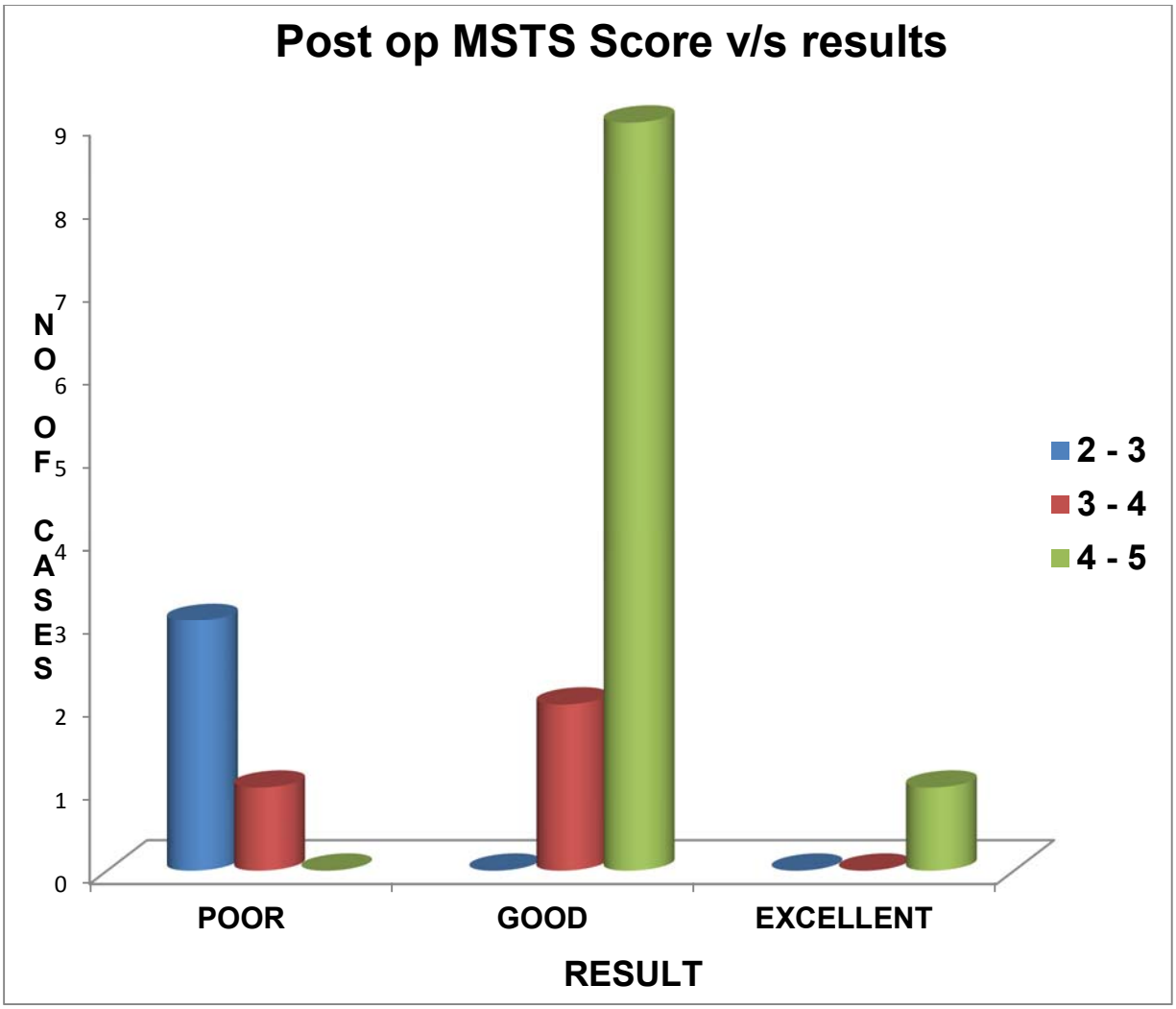


Table 14. Pre operative v/s post operative MSTS score analysis and its significance:

MSTS Score	Mean (N=16)	SD
Pre op	1.20	0.38
Post op	3.70	0.94
Mean difference	2.50	0.56
t-value*	11.26	
p-value	0.000	
Significant	Significant	

*Paired Samples Test

CONCLUSION

However, early improvement in functional status, better pain control, early ambulation and relatively much lesser complication rate, we strongly recommend surgical stabilization for pathological fractures.

Better results can be achieved with team approach including orthopaedic surgeon, oncologist, radiologist and physiotherapist.

The timing of the surgery is always of paramount importance in these patients. It solely depends up on the patients' general condition, however should be done at the very first safe opportunity.

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S. No	Name & IP No	Age years	Sex	Mode Of injury	Diagnosis	Primary cause	Date Of surgery	Time Delay In days	Procedure done	Surgical time	Complications	Follow Up	Pre op MSTS score	Post op MSTS score	Results
1	Mr Raman 49432	56	Male	Self fall at home	Basi cervical fracture neck of femur left side	Adenocarcinoma of colon	06.07.2012	14 days	Bipolar hemiarthroplasty	60 min	NIL	6 Months	1.2	4	Good
2	Mr Aundisamy 44889	67	Male	Self fall at home	Fracture shaft of femur right side	Bronchogenic lung carcinoma	08.09.2012	7 days	ORIF with Interlocking intramedullary nailing for femur	40 min	NIL	3 Months	1	4.2	Good
3	Mr Saravanan 294466	60	Male	Fall from two wheeler	Fracture shaft of femur right side	Small cell lung carcinoma	12.09.2012	25 days	ORIF with Interlocking intramedullary nailing for femur	40 min	NIL	Lost to follow up	1.4	5	Excellent
4	Mr Gani 55680	48	Male	H/O Back pain	Wedge compression fracture D12 & L 3 with paraparesis	Small cell lung carcinoma	05.11.2012	30 days	Posterior stabilisation D11 L1 , L2 L4 & biopsy	90 min	Post op infection	Lost to follow up	2	4	Good
5	Ms Swetha 22964	20	Female	Self fall	Pathological fracture left distal femur	Osteosarcoma of left distal femur			Wide excision of tumor and Installation of Custom made Mega Prosthesis (L) Distal femur	160 min	NIL	6 Months	0.8	3	Poor
6	Mr Raman 72433	62	Male	Fall from two wheeler	Fracture shaft of femur right, proximal third	Prostatic adenocarcinoma	26.08.2013	15 days	ORIF with Interlocking intramedullary nailing for femur	90 min	NIL	6 Months	1	4.2	Good
7	Mr Vignesh 120983	20	Male	--	Fracture right proximal tibia	Osteosarcoma of right proximal tibia	02.10.2013	2 Months	Wide excision of tumor and Installation of Custom made Mega Prosthesis right tibia	120 min	Recurrence	5 months	1	2	Poor
8	Ms Renugambal 120702	60	Female	Self fall at home	Subtrochanteric fracture right femur	Adenocarcinoma colon	28.10.2013	15 days	ORIF with Dynamic Condylar Screw fixation	60 min	NIL	6 months	1.6	4.2	Good

S. No															
9	Mr Karthik 6885	21	Male	--	Proximal humerus fracture left side	Osteosarcoma proximal humerus left side	22.09.2012	60 days	Wide excision of tumor and Installation of Custom made Mega Prosthesis left humerus	120 min	NIL	12 months	0.8	4.6	Good
10	Ms Muniyammal 5047	60	Female	Fall from height	Fracture L4, L5 vertebra with paraparesis	Carcinoma cervix (stage IIIb)	26.10.2013	10 days	Posterior stabilization and biopsy	60 min	NIL	6 months	1.2	2	Poor
11	Ms Padma 11235	37	Female	Chronic back ache	Fracture L1 vertebra without neurological deficit	Medullary breast carcinoma left side	05.02.2014	21 days	Posterior stabilization and biopsy	80 min	Death after 5 months	2 months	1	-	-
12	Mr Kathar 18842	26	Male	Fall from two wheeler	Fracture shaft of humerus right side	Rhabdomyosarcoma left thigh	06.03.2014	15 days	ORIF with plate osteosynthesis after resection of metastatic foci	120 min	NIL	6 months	2	4.2	Good
13	Mr Krishnan 7821	60	Male	Self fall at home	Fracture left distal femur	Chondrosarcoma of left distal femur	12.04.2014	15 days	Wide excision of tumor and Installation of Custom made Mega Prosthesis left distal femur	140 min	NIL	5 months	0.8	2	Poor
14	Ms Ranjitha 120334	20	Female	Self fall at home	Trans cervical fracture neck of femur left side	Giant cell tumour of left proximal femur	20.04.2014	30 days	Wide excision of tumor and Installation of Custom made Mega Prosthesis left proximal femur.	140 min	NIL	6 months	1.2	4.2	Good
15	Mr Subbiah 76657	67	Male	Self fall at home	Subtrochanteric fracture left femur	Renal cell carcinoma	12.06.2014	15 days	ORIF with Dynamic Condylar Screw fixation	120 min	NIL	4 months	1	3.8	Good

S. No	Name & IP No	Age	Sex	Mode Of injury	Diagnosis	Primary cause	Date Of surgery	Time Delay In days	Procedure done	Surgical time	Complications	Follow Up	Pre op MSTS score	Post op MSTS score	Results
16	Mr Arumugam	62	Male	Self fall at home	Pathological fracture shaft of right femur	Small cell lung carcinoma	22.03.2013	60 days	ORIF with Interlocking intramedullary nailing	120 minutes	Death after 4 months	2 months	1.2	-	-
17	Mr Kannan	60	Male	Self at home	Pathologicall Fracture shaft of right humerus	Multiple myeloma	12.02.2013	40 days	ORIF with excision of metastatic foci and BDCP fixation	120 miinutes	Death after 2 months	-	0.8	-	-
18	Ms Malliga	70	Female	Low back ache	Pathological fracture L2 with paraparesis	Medullary carcinoma of breast	15.02.2013	20 days	Posterior stabilization and decompression	100 minutes	Death after 3 months	-	0.8	-	-
19	Mr Murali	26	Male	Chronic swelling and pain in limb	Pathological fracture right distal femur due to primary osteosarcoma	Osteosarcoma of distal femur	06.03.2014	32 days	Wide excision of tumor and Installation of Custom made Mega Prosthesis for distal femur.	180 minutes	NIL	7 Months	1.2	3.8	Good
20	Mr Aundichamy	64	Male	Self fall at home	Pathological fracture neck of right femur	Small cell lung carcinoma	16.06.2012	15 days	Bipolar hemiarthroplaty right hip	60 minutes	NIL	12 months	1	4	good

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. K. Sunil Kumar,
Post Graduate, MS (Orthopaedics)
Institute of Orthopaedics & Traumatology,
Madras Medical College,
Chennai – 600003.

Dear Dr. K. Sunil Kumar,

The Institutional Ethics Committee has considered your request and approved your study titled **"FUNCTIONAL OUTCOME ANALYSIS OF SKELETAL STABILIZATION IN PATHOLOGICAL FRACTURES – A PROSPECTIVE & RETROSPECTIVE STUDY"** No. 03072014.

The following members of Ethics Committee were present in the meeting held on 01.07.2014 conducted at Madras Medical College, Chennai-3.

1.	Dr. C. Rajendran, M.D.	-- Chairperson
2.	Dr. R. Vimala, M.D., Dean, MMC, Ch-3.	-- Deputy Chair Person
3.	Prof. Kalaiselvi, MD., Vice-Principal, MMC, Ch-3	-- Member Secretary
4.	Prof. Nandhini, M.D. Inst. of Pharmacology, MMC, Ch-3.	-- Member
5.	Dr. G. Muralidharan, Director Incharge , Inst. of Surgery	-- Member
6.	Prof. Md Ali, MD., DM., Prof & HOD of MGE, MMC, Ch-3.	-- Member
7.	Prof. Ramadevi, Director i/c, Biochemistry, MMC,Ch-3.	-- Member
8.	Prof. Saraswathy, MD., Director, Pathology, MMC, Ch-3.	-- Member
9.	Prof. Tito, Director, i/c. Inst. of Internal Medicine, MMC	-- Member
10.	Thiru. Rameshkumar, Administrative Officer	-- Lay Person
11.	Thiru. S. Govindasamy, BABL, High Court, Chennai-1.	-- Lawyer
12.	Tmt. Arnold Saulina, MA MSW	-- Social Scientist

We approve the proposal to be conducted in its presented form.

Sd/Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

Member Secretary, Ethics Committee

PATIENT CONSENT FORM

STUDY TITLE: **Functional Outcome Analysis Of Pathological Fractures Treated With Skeletal Stabilisation**
A prospective & retrospective study

STUDY CENTRE: **Institute Of Orthopaedics And Traumatology**
Rajiv Gandhi Govt. General Hospital And Madras Medical College, Chennai-03

Patient's Name : _____

Patient's Age : _____

Identification Number : _____

Patient may check (√) these boxes

a) I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ☐

b) I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ☐

c) I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ☐

d) I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ☐

e) I hereby consent to participate in this study of "functional outcome analysis of pathological fractures treated with surgical stabilization" ☐

f) I hereby give permission to undergo detailed clinical examination, radiographs, diagnostic tests including hematological, biochemical and surgical procedure as required. ☐

Signature / Thumb impression _____ Place_____ Date _____

Of the patient.

Patient's Name &Address: _____

_____

Signature of the Investigator: _____ Place_____Date _____

Study Investigator's Name: **Dr K Sunil Kumar**

PATIENT INFORMATION SHEET

TITLE OF THE STUDY : **FUNCTIONAL OUTCOME ANALYSIS OF SKELETAL STABILIZATION IN PATHOLOGICAL FRACTURES.**

- A PROSPECTIVE & RETROSPECTIVE STUDY

We are conducting a study on **"Functional outcome analysis of skeletal stabilization in pathological fractures"**, among patients admitted in the Institute of Orthopaedics & Traumatology, Rajiv Gandhi Government General Hospital, Chennai.

The purpose of this study is to analyse the functional outcome in pathological fractures treated with surgical stabilisation.

We are selecting certain cases with pathological fractures secondary to malignancy or bone tumours and if you are found eligible we perform surgical stabilization with open reduction and internal fixation method and we evaluate the functional outcome of surgery.

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of Investigator

Signature of Participant

Date :

ஆராய்ச்சி ஒப்புதல் கடிதம்

ஆராய்ச்சி தலைப்பு

எலும்பு புற்றுநோயினால் ஏற்படும் எலும்பு முறிவிற்கு உள்பொருத்துல் அறுவை சிகிச்சை முறையில் சிகிச்சை செய்யும் பொழுது ஏற்படும் விளைவுகளைப் பற்றிய ஆராய்ச்சி

பெயர்	:	தேதி	:
வயது	:	உள் நோயாளி எண்	:
பால்	:	ஆராய்ச்சி சேர்க்கை எண்	:

இந்த ஆராய்ச்சின் விவரங்களும் அதன் நோக்கங்களும் முழுமையாக எனக்கு தெளிவாக விளக்கப்பட்டது.

எனக்கு விளக்கப்பட்ட விஷயங்களை நான் புரிந்துகொண்டு எனது சம்மதத்தை தெரிவிக்கிறேன்.

இந்த ஆராய்ச்சியில் பிறரின் நிர்பந்தமின்றி என் சொந்த விருப்பத்தின்பேரில் பங்கு பெறுகின்றேன். இந்த ஆராய்ச்சியில் இருந்து நான் எந்நேரமும் பின்வாங்கலாம் என்பதையும் அதனால் எந்த பாதிப்பும் ஏற்படாது என்பதையும் நான் புரிந்துகொண்டேன்.

நான் என்னுடைய சுய நினைவுடனும் மற்றும் முழு சுதந்திரத்துடனும் இந்த மருத்துவ ஆராய்ச்சியில் என்னை சேர்த்துக்கொள்ள சம்மதம் தெரிவிக்கிறேன்.

ஆராய்ச்சியாளர் கையொப்பம் **பங்கேற்பாளர் கையொப்பம்**

நாள் :
இடம் :

ஆராய்ச்சி தகவல் தாள்

தலைப்பு :

எலும்பு புற்றுநோயினால் ஏற்படும் எலும்பு முறிவிற்கு உள்பொருத்துதல் அறுவை சிகிச்சை முறையில் சிகிச்சை செய்யும் பொழுது ஏற்படும் விளைவுகளைப் பற்றிய ஆராய்ச்சி

சென்னை இராஜீவ்காந்தி அரசு பொது மருத்துவனையில், எலும்பு புற்றுநோயினால் ஏற்படும் எலும்பு முறிவிற்கு உள்பொருத்துதல் அறுவை சிகிச்சை முறையில் சிகிச்சை செய்யும் பொழுது ஏற்படும் விளைவுகளைப் பற்றிய ஓர் ஆய்வு இங்கு நடைபெறுகிறது.

முடிவுகளை அல்லது கருத்துகளை வெளியிடும்போதோ அல்லது ஆராய்ச்சியின் போதோ தத்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிடமாட்டோம் என்பதையும் தெயிரித்துக் கொள்கிறோம்.

இந்த சிறப்பு சிகிச்சையின் முடிவுகளை ஆராய்ச்சியின்போது அல்லது ஆராய்ச்சியின் முடிரின் போது தங்களுக்கு அறிவிக்கப்படும் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் **பங்கேற்பாளர் கையொப்பம்**

நாள் :
இடம் :

PATIENT PROFORMA

S.no: Name: DOA:

Age : Sex: Unit:

Occupation: Address: Economic status:

Timeof symptom onset :

Time of presentation :

Time of intervention :

DOA : DOS: DOD:

1.Chief complaints

2.History of presenting illness

3.Past history

4. Personal history

6. Obstetric history (females)

7. Family history

8. General physical examination

Vital signs

Pallor : Pulse :

Cyanosis : Blood pressure :

Clubbing : Respiratory rate :

Oedema : Temperature :

Jaundice : Hydration :

Lymph node:

9.Systemic examination

Cardiovascular system

Respiratory system

Central nervous system

10. Local examinations:

11.Investigations

HB: TC: DC: BT: CT:

ESR: Urea: RBS: Blood grouping and typing

Urine

Sugar: Albumin: Microscopy:

ECG

X-RAY- Chest X-ray PA view

Special blood tests:

- Serum calcium level-
- Phosphorus-
- Alkaline phosphatase
- Urine BJP-
- Serum protein electrophoeresis
- Thyroid profile-

Radiological investigations

- X ray AP & Lateral view of the affected part
- Whole body x ray survey
- CT scan of the involved area
- MRI of the involved area
- Bone scan
- USG abdomen and pelvis
- CT chest and abdomen

12. Preoperative diagnosis –

- Biopsy – (as planned)

13. Operative management -

14. Postoperative management :

Postop complications:

- Sepsis :
- Wound infection :

- Respiratory Infection :
- Renal Failure :
- Multi Organ Dysfunction :
- Mortality :

Length of hospital stay:

15.Condition at the time of discharge

16. follow up:

6 weeks :

3 month follow up :

6 month follow up :

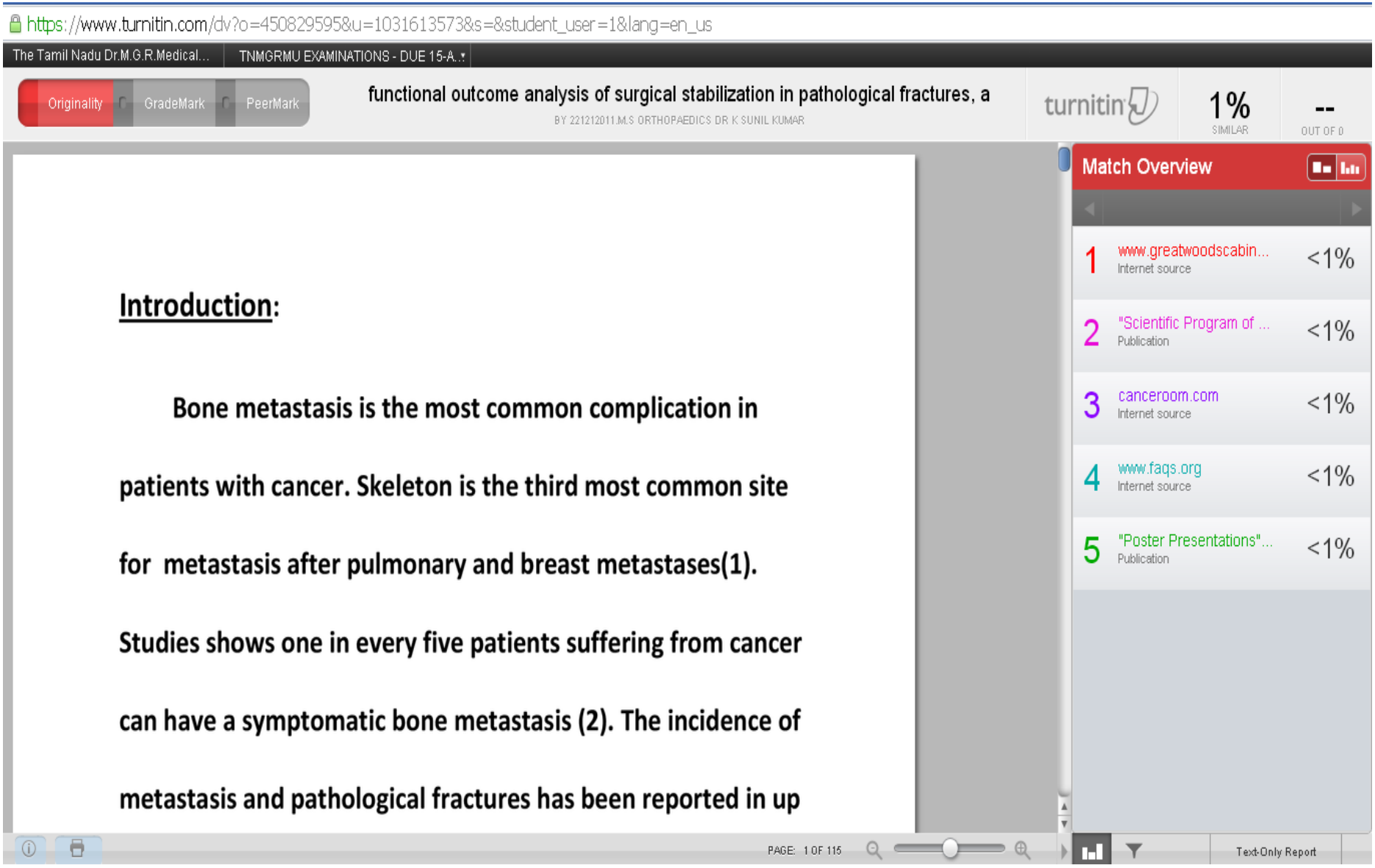
1 year follow up :

Function and Health Status in Surgically Treated pathological fractures

MSTS 1987 VERSION & MSTS 1993 version:
MSTS = Musculo Skeletal Tumor Society

MSTS	Pre operative	6 weeks post operatively	3 months post operatively	6 months post operatively	1 year post operatively
1987					
Motion					
Pain					
Stability					
Deformity					
Strength					
Functional activity					
Emotional acceptance					
1993					
Pain					
Function					
Emotional acceptance					
Walking aids					
Gait					
Walking					
Hand position					
Lifting					
Dexterity					

The 1987 version of the MSTS form evaluates seven parameters (mostly clinical) including pain, range of motion (ROM), joint stability, strength, deformity, general functional activity, and emotional acceptance. Each parameter is rated ex- cellent, good, fair, or poor according to specific guidelines. The overall result is expressed by combining the individual rating on each parameter (5 points maximum) for a maximum score of 35 points.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Bone metastasis is the most common complication in patients with cancer. Skeleton is the third most common site for metastasis after pulmonary and breast metastases(1). Studies shows one in every five patients suffering from cancer can have a symptomatic bone metastasis (2). The incidence of metastasis and pathological fractures has been reported in up
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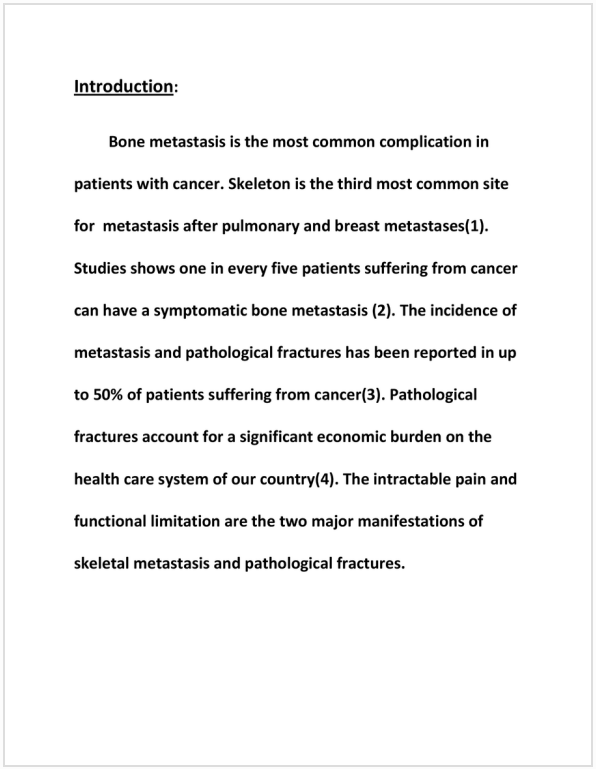

Introduction:

Bone metastasis is the most common complication in patients with cancer. Skeleton is the third most common site for metastasis after pulmonary and breast metastases(1). Studies shows one in every five patients suffering from cancer can have a symptomatic bone metastasis (2). The incidence of metastasis and pathological fractures has been reported in up to 50% of patients suffering from cancer(3). Pathological fractures account for a significant economic burden on the health care system of our country(4). The intractable pain and functional limitation are the two major manifestations of skeletal metastasis and pathological fractures.